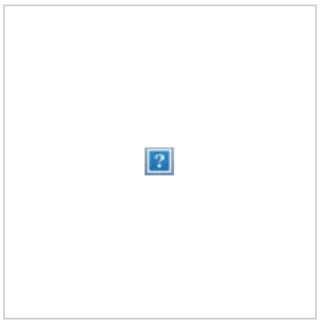
From: NutraIngredients-USA
To: Welch, Cara
Subject: ChromaDex scores big with Niagen / NPA voices concerns over Prop 65 change / Hard end points for prebiotics studies / Consumers want "natural," but don"t understand it / CRN hits membership record
Date: Thursday, January 28, 2016 12:23:06 PM



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Breaking News on Supplements & Nutrition - **North America**

28-Jan-2016

TODAY'S HEADLINES

ChromaDex closes deal to place Niagen in wide array of national chains

ChromaDex has hit another milestone in the market penetration of its Niagen ingredient with a deal that will put it into a number of national retail chains... Read

Prop 65: NPA responds to language of proposed Article 6 changes with 'significant concerns'

The Natural Products Association said in a release that the new Article 6 of California's Prop 65 would "limit consumer access, cost jobs, and harm the economy."... Read

SPECIAL EDITION: MICROBIOME METRICS & ADVANCES

Beyond microbiota: Prebiotics need hard health endpoints

Hard health endpoints, not just changes to microbiota, are needed to secure EU prebiotic health claims and bring fibre intakes up to recommended levels, according to European researchers... Read

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More consumers seek out products with 'natural' label, whatever it

means

A survey conducted last month revealed that 62% of Americans buy products labelled “natural,” thinking they are buying something they are not... Read

NEWS IN BRIEF

CRN adds 7 members, pushing organization to 'new record' size

The Council for Responsible Nutrition has announced the addition of seven new members. The additions push membership to “new record levels,” according to the organization... Read

All News Headlines for: January December November

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SPECIAL EDITION: TRANSPARENCY IN DIETARY SUPPLEMENTS

Should transparency be a priority for the supplements industry?

The NY AG’s probe into herbal supplements has done a lot to change the industry conversation over transparency, and some practices by some industry members cannot continue because they jeopardize the entire business community, say industry experts... Read

“A first, and necessary, step”: CRN to require members submit product labels to ODS label database

The Council for Responsible Nutrition (CRN) has announced it will require all of its members submit their supplement product labels to the Office of Dietary Supplements (ODS) Dietary Supplement Label Database (DSLD)... Read

Article that equates supplement industry with Big Tobacco called 'reckless' by former state AG

An article in a scientific journal that equates the dietary supplement industry with Big Tobacco has been called “scurrilous” and “reckless” by industry observers... Read

leading industry figures. Whether it relates to the supply chain, analytical testing, clai...

GLOBAL INDUSTRY NEWS

interhealth

Natural & Organic Health Association drops plans for "natural" seal

The Organic & Natural Health Association is abandoning its plan to create a certified seal that demonstrates when products are natural, but it remains dedicated to defining the widely used, but loosely understood marketing term. .. Read

UK shoppers pay 89% more for organic food: survey

UK consumers are paying an 89% premium for organic products at the major supermarkets, according to a survey, while more than half of organic shoppers think they pay too much... Read

SPECIAL EDITION: MICROBIOME METRICS & ADVANCES

Negotiating the balance: The host-microbiota relationship

Insights into the gut microbiome in recent years have greatly accelerated our understanding of the role the gastrointestinal tract has in human health, well-being and disease outcomes... Read

How do different dietary fatty acids influence body fat?

The way in which the body 'distributes' fat may be different depending on the dietary fatty acids consumed as well as genetic factors, Canadian researchers have found. .. Read

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» Way Better Snacks expands range and tips further growth in sprouted grains

» Yeast beta-glucan shows health-boosting benefits for children

» HMB decreased mortality among recently hospitalized, malnourished elderly subjects in study

» XOS alters microbiome of pre diabetic individuals in study

» Low-protein infant formula not detrimental to mental performance: Study

Production Manager
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- **Sustained Release, Spotlighted in Sports Nutrition** - INNOBIO Limited

From: NutraIngredients-USA
To: Welch_Cara
Subject: CRN & NPA submit comments on NDI draft guidance / 2016 special editions roundup / Robuvit"s liver benefits / Flax popularity / Probiotics for stress and anxiety
Date: Wednesday, December 14, 2016 1:07:45 PM

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14-Dec-2016

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TODAY'S HEADLINES

CRN asks FDA to broaden its view of what constitutes a dietary ingredient

The Council for Responsible Nutrition has urged the FDA to broaden the definition of dietary ingredients in its NDI draft guidance and to step back from requiring filings on new finished products... Read

NPA urges FDA to back off in applying food additive standards

The Natural Products Association has urged FDA to cease its attempt to apply food additive standards to dietary ingredients. To do so would create an undue burden on small business, many of which are represented by NPA... Read

Getting to know the supply chain: Lessons from 2016's special

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A year after the NY AG probe on botanical supplements, big calls for transparency came from both consumers and the industry. This year, we dedicated some of our in-depth coverage to transparency post-Schneiderman, as well as trends in contract manufacturing... Read

Minerals, botanicals, & Ayurveda: Lessons from 2016's special editions

Supplements are sourced from many parts of our planet. This year, we dedicated some of our in-depth coverage to ingredients from the land: Minerals, botanicals, and the ancient South Asian system of Ayurveda... Read

Study supports French oak wood extract's liver benefits

Supplementation with an extract from French oak wood may support liver function by boosting the elimination of toxins, says a new pilot study from Italy... Read

Flax rides rising popularity of gluten-free, vegan for 'resurgence' in food

Once considered primarily as a supplement for fiber and omega-3s, flax increasingly is appearing in more packaged foods with marketing claims extolling its health benefits and unique cooking properties... Read

Probiotics have a 'positive effect' on stress and anxiety: Meta-analysis

Probiotics consumption may have advantageous effects on mental health by lessening the psychological symptoms of perceived stress, depression and anxiety, according to a new systematic review and meta-analysis... Read

All News Headlines for: December November October

EDITOR'S CHOICE

Kemin & OmniActive resolve legal differences, begin to form Lutein and Zeaxanthin Trade Organization

OmniActive Health Technologies, Ltd. and Kemin Industries, Inc. have settled their legal disputes and will cross license 'use patents' on lutein, zeaxanthin and their isomers... Read

GUEST ARTICLE

Rehab, a Registry, and Steady Progress: The Year that Was

In many respects, 2016 will go down as the year that the unexpected and the improbable came to pass. For dietary supplements, however, the year was more predictable with a steady road toward rehabilitating its image tarnished from the prior year's events and flexing some political muscle to protect our consumers' access to our products... Read

Experts recommend kratom & CBD players file NDIs first, before asking for new product category

Some proponents of botanicals such as kratom or CBDs have chafed under regulatory restrictions that have forestalled wider acceptance and availability. But the full market is potentially available for those companies willing to go through accepted channels, experts say... Read

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CONTENT PROVIDED BY INTERNATIONAL PROBIOTICS ASSOCIATION

Evaluation of the State of Science Outside of Conventional Probiotic Usage Paper #1: Probiotics and Metabolic Syndrome

Metabolic disorders including hypertension, dyslipidemia, obesity and diabetes reflect a complex tangle of interfaces with the microbiota representing only one part of the multiple factors at play... Read

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Collaboration critical to combating malnutrition

The issue of poor or inconsistent standards of nutrition in hospitals and care homes continues to persist, with the elderly especially at risk of severe malnourishment.. Read

Nestlé USA to fight 'baseless' lawsuit over 'no preservatives' claims on Lean Cuisine

Nestlé USA is the latest in a series of food companies to be targeted by New York-based law firm Lee Litigation Group over its use of the label claim 'no preservatives' on products containing citric acid... Read

BioGaia expands in Japan with new probiotics deals

Swedish probiotics supplier BioGaia has signed two major deals in Japan with Nippon Kabaya Ohayo Holdings Inc. .. Read

PREVIOUS HEADLINES

» Omega-3s may turn off chronic low-grade inflammation in obese women: Study

» Collaborations, workshops and continuing outreach: IPA celebrates key achievements

» First take on NDI comments: Guidance will stifle innovation without increase in safety

» Riding on personalized nutrition wave, Care/of co-founders want to streamline the supplement shopping experience

» Companies, retailers must do more to make the healthy choice the easy choice, CSPI says

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- **What Is the Most Bioavailable, Organic Form of Magnesium?** - Albion
- **Biova Ingredients—The Clear Choice for Results** - Biova LLC
- **Aronox® – powerful, natural heart health benefits** - Naturex
- **Pioneering probiotics application in the Brain-Gut axis** - Lallemand Health Solutions: your probiotic solutions provider
- **US CONSUMERS INTERESTED IN FIBER TO IMPROVE HEALTH** - Sensus
- **Patented Lychee Extract for Sports Nutrition and RTD Applications** - Maypro Industries
- **UC-II® Joint Health Gummies** - InterHealth Nutraceuticals, Inc.
- **Are you launching a probiotic product to market?** - KGK Synergize Inc
- **NEM's Triple-action Joint Defense** - Stratum Nutrition
- **The #1 Clinically Evaluated Curcumin Brand Simply Does More** - Sabinsa Corporation
- **Strategic Nutrition for Eye Health** - Fortitech Premixes, by DSM
- **Glucoraphanin - Broccoli's Super Antioxidant** - Brassica Protection Products LLC

From: NutraIngredients-USA
To: Welch_Cara
Subject: CRN high on Gottlieb / NPA boosts multivitamins for WIC recipients / Herbalife boosts outlook / Thermogenic supplements for athletes / Vitamin D2, D3 link / ProbioKid safety recognized
Date: Tuesday, May 09, 2017 11:35:32 AM

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09-May-2017

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CRN's support of Gottlieb rises above standard level

The Council for Responsible Nutrition has enthusiastically supported the nomination of Dr. Scott Gottlieb as FDA commissioner in a letter to Senators... Read

NPA advocates use of WIC funds to cover multivitamins

The Natural Products Association has sent letters to Congress supporting the use of federal nutrition funds to allow families to purchase multivitamins... Read

Herbalife shrugs off FTC, Ackman; boosts 2017 outlook

Herbalife has shaken off the lingering effects of a big-ticket settlement with the Federal Trade Commission with a relatively solid quarterly results statement that was welcomed by stock traders... Read

CELSIUS launches new line of 'thermogenic' liquid supplements for athletes

With 300 mg of caffeine and 2,000 mg of L-Citruline, CELSIUS' new line HEAT targets athletic

trainers, body builders, military personnel, and endurance athletes for accelerated metabolism and an energy boost... Read

'Complex link' between vitamin D2 and D3 supplementation

A new study may shed light on the differences in uptake of vitamin D variants, while also revealing absorption is higher in women than men, and two-weekly dose regimens are the most effective... Read

NEWS IN BRIEF

ProbioKid probiotic strains recognized safe in US and Canada for use in young children

The probiotic strain blend ProbioKid by Lallemand has received a Natural Product Number (NPN) from Health Canada, while the GRAS status is still only self-affirmed in the US... Read

All News Headlines for: May April March

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SPECIAL EDITION: SPORTS NUTRITION

What's driving US sports nutrition in 2017? Blurring categories, casual users, and Instagram

The US sports nutrition market in 2016 posted a value growth of 12%, according to market analytics firm Euromonitor, dubbing it as 'another good year for the category.'.. Read

BC30 may enhance muscle benefits of HMB during military training: RCT

The muscle and anti-inflammatory benefits of HMB may be enhanced by combining the ingredient with the BC30 probiotic, says a new study with soldiers from the Israel Defense Force... Read

Most NZ fish oil supplements meet label claims, oxidation levels: GOED analysis

Testing of 47 fish oil supplements purchased at retail in New Zealand shows that 91% met

EPA/DHA label claims, according to strict GOED standards, while most also met regulatory limits for oxidation. .. Read

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Paper #2: Inflammatory Conditions

Individual microbiomes may influence tendencies to autoimmune diseases and inflammatory conditions including arthritis and fibromyalgia... Read

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Vitamin K2 MK-7: A stability challenge, a market study

Demand for vitamin K2 has increased rapidly over the past decade as awareness of its role in bone and cardiovascular health has spread. However, studies run by Kappa Bioscience show many K2 products contain lower-than-claimed levels of the vitamin, a finding that threatens to undermine the market and its products' ability to provide health benefits and slow the natural effects of aging... Read

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All the social media highlights from Geneva... Read

Muscles 'taste' their way towards regulating blood sugar levels: Mice study

The body's regulation of blood sugar levels is aided by skeletal muscles, a study has identified, in a mechanism that appears to identify its ability to 'taste' or 'sense' glucose in the body. .. Read

As more Americans search for 'premium' meats, US sales of Prosciutto di Parma grew 39% in last three years

In the competitive meat category, US shoppers are increasingly eyeing premium options—a momentum which Prosciutto di Parma is riding on... Read

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» Vitamin E tocotrienols may improve metabolitic profiles in older women

» Study supports spearmint extract's anti-inflammatory potential: Neumentix data

» Polyphenol-rich extracts may improve physical performance during exercise: RCT

» Indena and Hyris partner on portable genomic identification of botanicals

» FDA uses warning letter to check up on DMAA recall

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- **RED ORANGE COMPLEX® protects against photo-induced skin hyperpigmentation** - BIONAP Srl
- **Balancing Innovation and Risk in Sports Nutrition Ingredients** - NSF-International
- **FUROCYST® - FOR WOMEN'S HEALTH** - Chemical Resources (CHERESO)
- **DuPont™ probiotics proves effect on Immune Function in Elderly Subjects** - International Probiotics Association
- **Biootic™ , the probiotic yeast for health** - Gnosis USA Inc.
- **Sinetrol® - Fat Shredding Technology™: New clinical study** - Fytexia
- **Adulteration 101: Lessons Learned** - Sabinsa Corporation
- **The smart solution for cognitive health products** - Frutarom Health
- **The Modern Athlete, Concepts & Formulations** - Sabinsa Corporation
- **Build A Weight Loss Brand Consumers Can Trust** - PLT Health Solutions
- **Discover a New Anti-Aging Solution for Natural Product Formulations** - Maypro Industries

From: NutraIngredients-USA
To: Welch_Cara
Subject: CRN on malnourished Americans / NPA seeks NDI extension / Saliva test for NO / Oak extract boosts triathlon performance / Tea catechins studied for blood sugar effects
Date: Monday, August 29, 2016 10:56:44 AM

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29-Aug-2016

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CRN talks about the "over fed and under nourished" problem in the US

There are increasing cases of malnutrition and nutrition deficiencies in a developed country like the US, recent studies report. We chat with an expert to get his analysis... Read

NPA asks for NDI comment period extension

The Natural Products Association is asking FDA to add 30 days to the comment period on the updated New Dietary Ingredients draft guidance... Read

Saliva test strips help consumers, athletes optimize NO levels

Berkeley Test has firmed up the IP surrounding its nitric oxide testing method with the grant of a US patent. The test, which has already been used by athletes and trainers, can help mainstream consumers validate improvements in their diet and metabolic health, a company exec said... Read

Robuvit supplementation may improve triathlete performance

Supplementation of Robuvit for two weeks cut amateur triathletes' total event times by 11%, researchers in Italy suggested... Read

Diabetes game changer? Researchers to look at green tea catechins & insulin

Botanical supplier Plandaí Biotechnology has signed a research agreement with North West University in South Africa to investigate green tea catechins and type 2 diabetes. .. Read

All News Headlines for: August July June

RESEARCH STUDY

Pycnogenol® Improves Fitness and Muscle Recovery

Published studies show daily supplementation of Pycnogenol® is effective in boosting muscle performance, increasing endurance and reducing cramping and soreness by controlling oxidative stress in recreational athletes and triathletes....

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SPECIAL EDITION: ALGAE

Expert says algae's promise still huge despite disappointments in ingredient development

Algae companies have a habit of over promising and under delivering. According to one longtime expert in the field, that's almost by default, resulting from the organisms' almost unlimited potential and the limited ability of current technology to realize that promise... Read

Self-affirmed GRAS omitted from new NDI draft guidance

The devil is in the detail, and one detail easily missed in the new draft guidance for new dietary ingredient notifications is that self-affirmed GRAS is no longer mentioned as an 'alternative' to an NDI notification... Read

OmniActive builds science for Lutemax 2020 for eye health

OmniActive Health Technologies is investing heavily to deepen and broaden the scientific substantiation for its eye health ingredients, with new studies supporting the bioavailability, visual function, and benefits against the detrimental effects of digital screens... Read

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Grass-fed claims on products are a beacon for consumers who are health-conscious, want minimally processed food and care about animal welfare, and as such manufacturers increasingly are using them on products across categories and channels to drive up sales sharply... Listen now

EU rejects more than 90% of all health claims: Study

The EU has authorised only a small fraction of the health claims submitted to it, with a number of categories seeing no authorised claims at all, according to a new analysis of the bloc's uber-strict health claim process... Read

Males with more muscle don't need more protein, study finds

More protein intake equals more muscle growth, according to a Scottish study, but the amount of growth does not depend on an individual's overall muscle mass... Read

Amazing Grass unveils organic 'superfood' bars

Plant-based powered nutrition company, Amazing Grass, has added two flavors to its organic 'superfood' bar line with a new packaging that highlights its whole-food ingredients... Read

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NutraIngredients-USA Sports Nutrition Forum 2016

Tune in for expert insight from Mintel, Bodybuilding.com, Douglas Labs, and the International Society of Sports Nutrition on the latest market and science trends in sports nutrition today. Join us on April 23, to register... Click Here

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» Cardax puts synthetic astaxanthin finished product on market

» Literature from trade show booth puts company in hot water with FDA

» Embracing the future: The dietary supplement industry comes of age

» Can shrimp byproducts be a source of shelf-stable astaxanthin?

» Cordyceps fungi supplementation may improve high-intensity exercise

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Thinking of a clinical study to substantiate your claims? - KGK Synergize Inc

Natural Collagen Synthesis for Sports Nutrition and Anti-Aging - Natreon Inc.

From:	Benjamin, Dianne
To:	Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com; mmcguffin@ahpa.org; melville@chpa.org
Cc:	Welch, Cara
Subject:	CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting: 9/28 12:30pm --Security Forms, Map and LobbyGuard --please distribute
Date:	Monday, September 28, 2015 6:29:46 AM
Attachments:	Scheduled Visit Notification from .msg Parking.pdf

Good morning - you are confirmed to meet with Mike Taylor on Monday, 9/28 at 12:30pm.

The meeting will be held at our White Oak offices - 10903 New Hampshire Avenue, Silver Spring, MD 20993. Please note, you'll be entering the campus via the main entrance/Building 1 off Mahan Road. Please bring your U. S. Government issued ID with you for check in.

If arriving by private car, I've attached a map of the campus which also indicates where visitor parking is located. There's a shuttle bus available that can bring you to Building 1. Please arrive at least 15 minutes early to allow for travel to the main entrance, security and escort to the conference room.

I've also attached a form that when presented to security, will make for easier entry into our building. There's no issue if you aren't able to print it out. Also, all participants are accounted for on the attached form.

When you arrive, please ask the guard to call Nicole Clapp as she'll escort you to Mike's office. Her number is 301-796-4500 I if needed. Please let me know if you have any questions.

Best Regards,

From: Welch, Cara
Sent: Thursday, September 10, 2015 4:21 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert; Benjamin, Dianne; Clapp, Nicole
Subject: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm

All,
We've scheduled a meeting to discuss dietary supplement issues with your 5 trade associations on Monday, Sept 28, at 12:30pm. We have an hour scheduled for the meeting and it will be at the White Oak campus. I apologize for the slight time change from what I proposed before – Mike's schedule was adjusted in the last couple weeks.

When your initial request for a meeting came in a couple months ago, you'd requested a meeting to discuss elevating DDSP from a division to an office and the matter of a joint industry-FDA symposium examining dietary supplements. I'm not sure if these are still your agenda items but I think we'd like a meeting to discuss how to elevate and redefine dietary supplement regulation and opportunities

for FDA collaboration. Please let me know if you have additional items you'd like included.

Finally, I've copied Ms. Dianne Benjamin from OFVM's Executive Secretariat Staff – she'll coordinate agenda, materials, and other preparation as needed.
Thank you all
Cara

From: Welch, Cara
Sent: Friday, September 04, 2015 3:20 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

All, I just wanted to touch base on this request – I've heard from some of the associations but hope to get a meeting scheduled on Mike and Ted's calendars right away next week. Please let me know if the two times offered below are acceptable.
Thank you and I hope everyone has a good holiday weekend.
Cara

From: Welch, Cara
Sent: Monday, August 31, 2015 2:12 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Michael, Scott, Steve, Dan, and Loren,

I hope you're all well. DDSP wanted to reach out re: scheduling a meeting with Mike Taylor, Ted Elkin, DDSP, and others at OFVM on the topics mentioned below. Due to the busy schedules of Mike and Ted, as well as the desire to get this meeting scheduled soon, I can only offer Monday, 9/28, at 1-2pm or 4:30-5:30pm. Please let me know as soon as possible if one of these dates can be accommodated – we will certainly have a call-in option if folks can't attend in person.

Thanks
Cara

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway

From: Mozersky, Robert
To: CFSAN-ODSP
Subject: Emailing: NPA Subm ts Wish List For Reduc ng FDA Regulatory Burdens Per Trump Order Rose Sheet.htm
Date: Thursday, December 14, 2017 8:51:02 AM

NPA Submits Wish List For Reducing FDA Regulatory Burdens Per Trump Order

12 Dec 2017
NEWS

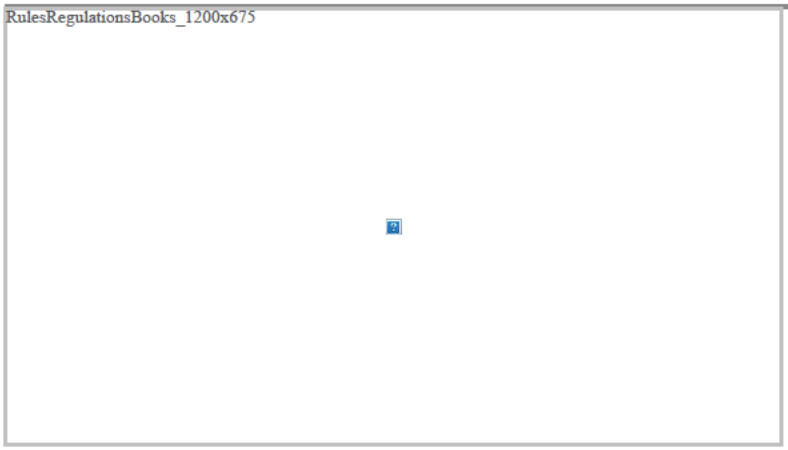
Eileen Francis

Eileen Francis eileen francis@informa com

Executive Summary

FDA's NDI notification draft guidance should be rewritten and its Nutrition Facts and Supplement Facts Final Rule delayed, the Natural Products Association says

in comments submitted to the agency in response to President Trump's executive order aimed at cutting down on burdensome regulations



FDA's new dietary ingredient notification draft guidance should be rewritten and its Nutrition Facts and Supplement Facts final rule delayed as the regulatory measures burden US businesses and allow Chinese competitors to reap the greatest rewards, the Natural Products Association recommends

FDA requested comments from stakeholders in regulated industries early in 2017 following executive orders early from President Trump aimed at reducing regulatory burdens on industry and managing costs associated with compliance

The orders, taken together, direct each federal agency to establish a Regulatory Reform Task Force to evaluate existing regulations and identify at least two that can be eliminated for each new regulation issued (Also see "Trump Order Reducing Regulation Might Imperil FDA Good Guidance Practices" - Rose Sheet, 30 Jan, 2017)

NPA President and CEO Dan Fabricant welcomes the initiative at FDA, stating in the group's Dec 7 comments to the Center for Food Safety and Applied Nutrition that "the implementation of burdensome regulations over the past five years failed to include accurate economic impact analyses with proposed rules, final rules, and Level 1 guidance documents; and some regulations fail to protect the public and should be changed "

In particular, CFSAN's NDI draft guidance and Nutrition and Supplement Facts final rule, among other cited regulations and guidances, represent undue burdens for NPA's members – particularly smaller companies – and hamper their ability to compete in the natural products space, Fabricant says

They are prime targets for cuts or overhauls, he suggests

> "I actually think it is just plain wrong as a matter of law in many instances, and its requirements that it is attempting to impose through a guidance document [are really] nothing more than a set of regulations." – Venable partner Todd Harrison on FDA's NDI notification draft guidance

Fabricant notes that the natural products market is booming, with the US opportunity expected to grow roughly 9% annually to $252bn by 2019, reflecting American consumers' increasing appetite for wholesome products and ingredient transparency

However, due to the tightening "stranglehold" of US regulations, much of that demand will not be captured by domestic businesses going forward, according to Fabricant Chinese companies in particular are pouncing to "fill the void" left by US businesses unable to compete, the exec suggests

He points out that the US Commercial Service, the trade promotion arm of the Department of Commerce's International Trade Administration, has estimated more than 3,000 Chinese manufacturers producing more than 4,000 types of supplements

"China has abundant skilled and unskilled labor, low-cost facilities, and above all, government incentives in the form of reduced regulatory burdens," Fabricant says

Trump has made US-China trade a leading priority given what he sees as "the chronic imbalance in our relationship as it pertains to trade " Ostensibly, NPA aims to add to that discussion with its comments and potentially strike a chord that resonates to the White House

NDI Draft Guidance

FDA's draft guidance on NDI notifications is a not surprising choice for industry advocates to include in proposals for regulatory burden reductions

When the agency issued an initial draft guidance in 2011, industry groups blasted it as an impediment to product development From their point of view, it set out criteria for new ingredients that were not supported by the Dietary Supplement Health and Education Act (Also see "FDA Revision Of NDI Draft Guidance Starts With Grandfathered List" - Rose Sheet, 25 Jun, 2012)

Industry was more receptive to a 2016 revised draft, saying that while much work remained, FDA had at least addressed some of industry's concerns Notably, the agency said it would work with industry on developing a list of old dietary ingredients marketed prior to the Oct 15, 1994 implementation date for DSHEA, which would exempt them from NDI filing notifications (Also see "Revised NDI Notification Draft Guidance Shrinks Divide Between FDA And Industry" - Rose Sheet, 11 Aug, 2016)

NPA last month introduced its own recommended list of old dietary supplement ingredients that it says are eligible for grandfathering, based on magazines and newsletters published prior to 1994 Its list is being positioned as a "guidepost" for companies as they determine which substances likely require NDI notification (Also see "NPA Pre-DSHEA Ingredients Book: First Chapter In FDA's Industry-Sourced Reading?" - Rose Sheet, 10 Nov, 2017)

FDA remains noncommittal with respect to NPA's book, stating interest in reviewing the group's methodology while underscoring that it has not verified the list's accuracy

Such uncertainty aside, NPA says the agency's draft guidance raises "significant" concerns regarding economic impacts on manufacturers of finished products and suppliers of dietary ingredients

Based on NPA's research, companies currently pay an average upwards of $518,000 for one NDI notification, which does not account for additional testing FDA has proposed for NDI submissions in its draft guidance

The testing FDA seeks – akin to that required for food additives and GRAS substances, which must meet a stringent "reasonable certainty of no harm" standard – is out of balance with what should be required in the NDI notification process and threatens to hamstring supplement companies, according to Fabricant

“FDA has neither presented not indicated that a fair, accurate economic impact analysis will be conducted to assess the burden to businesses,” he says, suggesting that while an NDI guidance is "important," it must take into account the realistic costs of compliance

“NPA believes the failure by FDA to conduct this critical impact analysis would be detrimental to small dietary supplement companies, preventing their innovative ingredients from reaching the marketplace Small business would not be able to sustain these high costs to complete food additive-level toxicology testing discussed in the revised draft guidance," Fabricant adds

Todd Harrison, a partner in the DC office of law firm Venable LLP who chairs his firm’s FDA group and counsels dietary supplement companies on regulations, agrees that the NDI guidance is overly burdensome

“I actually think it is just plain wrong as a matter of law in many instances, and its requirements that it is attempting to impose through a guidance document [are really] nothing more than a set of regulations,” he said in a Dec 12 email

Nutrition/Supplement Facts Rule

After pushing for a repeal of the Nutrition Facts and Supplement Facts final rule in comments submitted to FDA in early 2017 and via a mid-year citizen petition, NPA is now pressing FDA to withdraw the final rule until it can be evaluated to determine whether changes it requires on labels are necessary and just how costly they will be to small businesses

FDA published the final rule in May of 2016, incorporating changes informed by comments on a proposed rule issued in July 2015 It stands to impact the Nutrition Facts panel for foods, which include products such as nutrition bars and energy drinks, as well as the Supplement Facts label for dietary supplement products

Among its provisions, the rule establishes a definition for “dietary fiber,” one of the ingredients required on Nutrition Facts and Supplement Facts labels With the definition, some ingredients long considered fiber by industry no longer qualify, and the recommended daily intake of fiber also is changing, increasing to 28g from a previous recommendation of up to 25g

NPA is asking the agency to remove the definition for fiber, among other targeted requests related to the final rule (*see chart below*)

NPA also has argued against the rule’s requirement that nutrition and supplement facts labels feature “Total Sugar” instead of “Sugar” with an indented subhead below stating the amount of added sugars, measured in grams and also as a percent of daily value

The “Food Labeling: Revision of the Nutrition and Supplement Fact Labels” rule was slated to go into effect on July 26, 2018,for firms with more than $10m in annual sales and a year later for firms with less lower sales However, in September the agency extended those compliance dates to January 2020 for larger firms and 2021 for companies with less than $10m in sales per year

NPA requests extending the compliance dates to July 2021 and 2022

“NPA believes that a 3-year extension in the compliance date for these two final rules is sufficient time for the agency to conduct proper empirical studies involving consumer research” to demonstrate that the changes are needed, Fabricant writes, noting that CFSAN has a division dedicated to conducting such research, though the group is “rarely” used

“NPA feels this group is positioned appropriately to conduct such empirical research studies to support the change FDA has imposed on the food and supplement industries," the NPA head says

Harrison agrees many changes required under the rule “simply make no sense and will actually mislead consumers into thinking certain foods are more healthy than others” when that is not the case

For example, the “added sugars” declaration may mislead consumers into thinking one item is healthier than another simply because it does not have “added sugars," when in reality it still could be “full of simple sugars which could have the same impact on health "

During a Food & Drug Law Institute webinar in 2016, EAS Group Senior Consultant said the Nutrition Facts and Supplement Facts final rule, from a marketing standpoint, is full of “landmines and unintended consequences” that will affect numerous products on the market (Also see "'Landmine' Of Consequences In Nutrition, Supplement Facts Label Changes" - Rose Sheet, 22 Jul, 2016)

CFSAN’s comment deadline for stakeholders to provide input on the Trump-ordered regulatory streamlining initiative was initially set for Dec 8, but FDA extended the deadline an additional 60 days Both the Council for Responsible Nutrition and the Consumer Healthcare Products Association plan to provide comments by the later date

From the editors of the Tan Sheet. Our dietary supplement industry coverage now is published in the Rose Sheet, with articles emailed to readers daily and available on this page of the Rose Sheet website.

NPA’s Proposed Regulatory Fixes

FDA/CFSAN Regulation or Guidance	Provision	NPA’s Concern	Proposed Solution
FDA Color Additive Regulation – Use of Chlorophyll as a Coloring Agent in Capsules	Chlorophyll can be used as a dietary ingredient in contents of capsules, but is not permitted to be used to color the capsule	Lost revenue from not being able to incorporate chlorophyll as part of a capsule	Remove the restrictive regulation that only allows ingredient to be used in citrus-based dry beverage mixes Permit use as part of the dietary supplement capsule
FDA Draft Dietary Fiber Guidance, promulgated from the Nutrition and Supplement Facts Final	Non-digestible carbohydrates must be supported by human clinical trials to substantiate their role	FDA’s new definition for dietary fibers sets up overly burdensome regulatory barriers for many dietary fibers to enter the market and economically impacts many companies that manufacture non-digestible isolated or synthetic carbohydrates that previously could be declared	Remove the new definition of dietary fiber from any new nutrition and supplement facts final

Rule	as a dietary fiber	as "dietary fiber " It is economically unviable (nearly $2m for two randomized clinical trials) for a company to meet FDA's standard and "scientifically absurd "	rulemaking
FDA Nutrition and Supplement Facts Final Rule	Firms selling probiotic dietary supplements must list the total quantity by weight per serving of their live microbial ingredients in metric units	While this makes sense for dietary ingredients that do not convey activity, it does not make regulatory sense for dietary ingredients in which activity is an essential parameter to convey to consumers Metric units for probiotics does not convey the necessary serving level information of activity	Probiotics and other dietary ingredients where conveying "activity" to consumers is important should be listed with units of activity rather than metric units
FDA Nutrition and Supplement Facts Final Rule	Nitrogen-containing compounds that are not used in protein synthesis can be used under the current regulations toward the calculation of protein content	The present regulation for protein content could lead to economically motivated adulteration of products	The current protein calculation should have stricter parameters and guidance on how to calculate protein content The nitrogen content of any non-amino acids or amino acids not incorporated into protein should not be used in the final calculation of total protein content
Draft Guidance for Industry: New Dietary Ingredient Notifications	FDA proposes to ban dietary supplement ingredient vinpocetine through an administrative proceeding	Many small businesses with brands selling vinpocetine would be economically impacted	FDA should withdraw the administrative proceedings on vinpocetine from the record by issuing a notice in the Federal Register

Table

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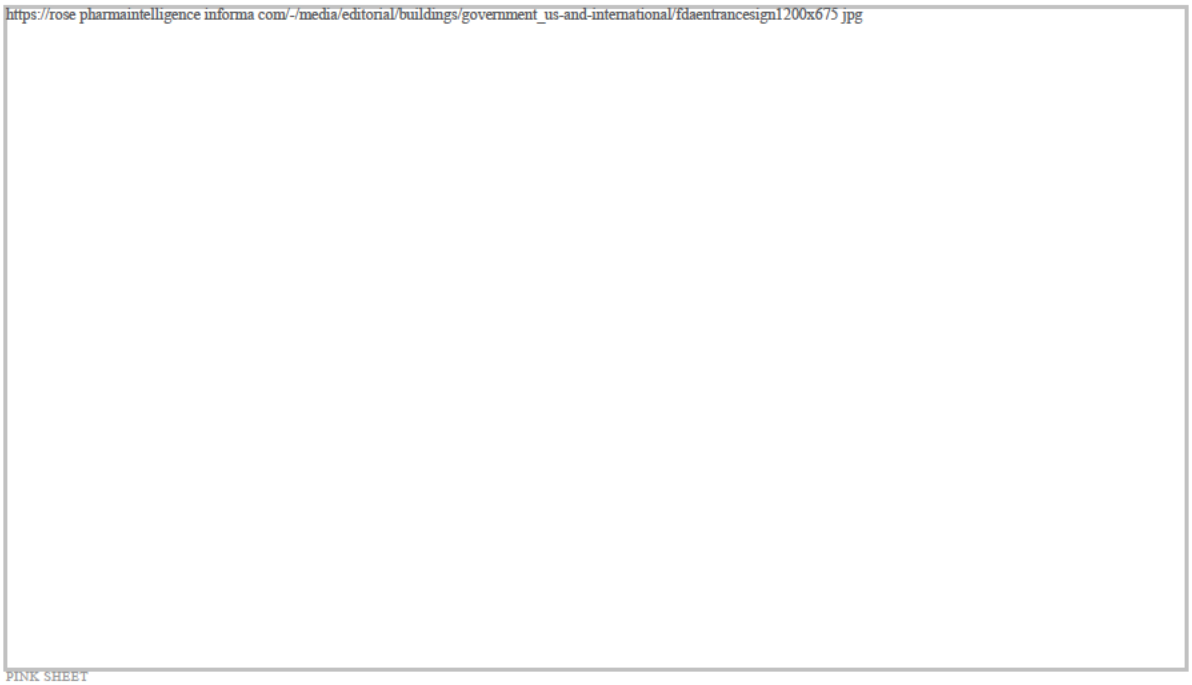
10 Nov 2017



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From: NutraIngredients-USA
To: Welch_Cara
Subject: Fabricant & NPA sued / Folate supplementation / Kemin"s ZeaOne approved / Nordic diet benefits / Tax credit / Energy /
Date: Monday, February 01, 2016 1:40:12 PM

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[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).

[1] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

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[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).

[2] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

From:	Durkin, Robert
To:	Welch, Cara
Subject:	FW: AHPA NPA Joint Letter
Date:	Tuesday, September 15, 2015 8:14:12 AM
Attachments:	08312015 - AHPA and NPA joint letter.pdf

We should get together and start to flesh out a response…….

From: Welch, Cara
Sent: Monday, August 31, 2015 1:40 PM
To: Durkin, Robert
Subject: FW: AHPA NPA Joint Letter

From: Corey Hilmas [mailto:corey.hilmas@npainfo.org]
Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
Subject: AHPA NPA Joint Letter

Dear Dr. Welch and Ms. Robinson,

The American Herbal Products Association (AHPA) and the Natural Products Association (NPA) have drafted a joint letter requesting clarification on the labeling of an herbal dietary ingredient for use in dietary supplements, pursuant to 21 CFR 101.4(h). We hope that you would be able to shed light and provide direction on this issue for us.

Sincerely,

Corey J. Hilmas, M.D., Ph.D.
Senior Vice President of Scientific & Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office 202.223.0101 x109
Direct 202.204.4725
Cell 443.632.8365
Fax 202.223.0250
www.NPAinfo.org

From:	Bunning, Vincent
To:	Durkin, Robert; Tave, Steven; Welch, Cara
Subject:	FW: FCN: NPA petitions FDA to stay Nutrition Facts labeling rule, not just delay it
Date:	Tuesday, June 20, 2017 10:23:27 AM

From: Bunning, Vincent
Sent: Tuesday, June 20, 2017 10:22 AM
To: Musser, Steven M; Bunning, Vincent; Diachenko, Gregory W; Callahan, John; Noonan, Gregory; Rader, Jeanne I *; Pawar, Rahul
Subject: FCN: NPA petitions FDA to stay Nutrition Facts labeling rule, not just delay it

Legal & Regulatory / Labeling & Advertising / NPA petitions FDA to stay Nutrition Facts labeling rule, not just delay it

NPA petitions FDA to stay Nutrition Facts labeling rule, not just delay it

By Joan Murphy
http://www.agra-net.com/agra/food-chemical-news/legal-and-regulatory/labeling-and-advertising/npa-petitions-fda-to-stay-nutrition-facts-labeling-rule-not-just-delay-it-554799.htm?CTR=DNART
Published: June 20, 2017 02:07 PM

FDA should not just delay the Nutrition Facts label rule, it should withdraw it because it's costly and unnecessary, the Natural Products Association (NPA) says in a petition sent to FDA June 16.

The 22-page **petition** has a list of grievances that should sideline the final rule, the dietary supplement association says. FDA's final labeling rule is inconsistent with the new administration's regulatory agenda, presents serious First Amendment issues, includes a Daily Value (DV) for added sugars that was not in the proposed rule, is inconsistent with the findings of its own consumer studies, is not supported by eye-tracking studies and includes an "unjustified" new definition of dietary fibers, the petition says.

NPA also criticizes FDA for failing to submit an economic impact analysis on the new cost burden to food and supplement businesses, says the petition filed by Richard Oparil, a principal of Porzio, Bromberg & Newman and counsel to NPA.

At the request of industry, FDA **announced** June 13 it was extending the compliance dates for the required Nutrition Facts panel changes to give food companies more time to make changes.

FDA Commissioner Scott Gottlieb said the new compliance date for the labels would follow in a future *Federal Register* notice. “This is a TIME LIMITED delay to provide more guidance,” Gottlieb said on Twitter.

The initial compliance date for the Nutrition Facts and Supplement Facts Label and Serving Size final rules – which were finalized in May 2016 – were set for July 26, 2018, with an additional year to comply for manufacturers with annual food sales of less than $10 million. But food and supplement companies asked FDA to delay the rule, citing costs, lack of guidance, problems with the new dietary fiber definition and the need to coordinate with the looming label change for genetically modified organisms (GMO) disclosures.

NPA’s petition says FDA should have allowed public comment on the new DV for added sugars in a proposed rule, rather than inserting it in the final version, and should not have used a dietary guidelines committee recommendations to develop the 50g Daily Recommended Value (DRV) for added sugars. In the end, the final label may confuse consumers when added sugars are isolated from total sugars on the new panel.

Among the problems with the new definition of dietary fibers, FDA appears to require two clinical trials to demonstrate a beneficial physiological effect in humans in order to pass this regulatory hurdle just to be called a dietary fiber, the petition says.

“This new regulatory process created by FDA to amend the list of accepted dietary fibers is overly burdensome to the food and supplement industry and does not serve to protect consumers,” NPA says. “In order to declare ‘dietary fiber’ on the label, industry must spend and waste nearly a million dollars or more just to list that ingredient as contributing to dietary fiber. This is an example of regulation that lead to neither higher quality nor greater safety to consumers.”

NPA President and CEO Daniel Fabricant said the Trump administration should set its sights on the labeling rule because it violates the new regulatory agenda.

“We are heartened by the administration’s pledge to weed out bad regulations that only end up costing consumers more money, and this one is exhibit A,” Fabricant said Monday. “This rule was poorly-written, rushed, unnecessary, and should be shelved immediately. Labeling is extremely important, but labeling changes posed by FDA must be material and based on scientific evidence or consumer empirical studies, and not based on whim or the way the wind happens to be blowing.”

From: DosSantos, Mariton
To: Welch, Cara
Subject: FW: Invitation to speak at a NPA Webinar
Date: Wednesday, August 06, 2014 5:42:34 PM

Cara,

This is Lauren email about the webinar.

-Daniel

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Friday, August 01, 2014 4:09 PM
To: DosSantos, Mariton
Cc: Vicki Whitsitt
Subject: RE: Invitation to speak at a NPA Webinar

Hi Dr. dos Santos,

We are thrilled to have you join us for the August webinar. Thank you so much for sending over your bio and headshot.

The topic of the webinar is understanding claims targeted by the FDA During Inspections and Import Entry Reviews. I've included a description below.

You and Dr. Hilmas will have the opportunity to speak for 30-40 minutes and we'll do 20-25 minutes of Q&A.

In the past six months, the U.S. Food and Drug Administration (FDA) has stepped up its efforts to detain products making immune, inflammation, blood sugar and a variety of other claims. Join the Natural Products Association (NPA) on **Wednesday, Aug. 20** for an all-new webinar and learn how you can avoid having the agency take action against your products.

In **Understanding Claims Targeted by FDA During Inspections and Import Entry Reviews**, you'll hear from the FDA's former expert on claims and NPA's current Senior Vice President of Scientific and Regulatory Affairs Corey Hilmas, M.D., Ph.D. In addition, Dr. Hilmas will be joined by the agency's point of contact for structure/function notifications, Mariton "Daniel" dos Santos, PharmD, Ph.D., in the Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (CFSAN), FDA.

Dr. Hilmas and Dr. dos Santos will discuss:

- What is permitted for immunity, inflammation, blood sugar and other claims, and what is not permitted and why
- An overview of the detention process from import entry to refusal
- The difference between express and implied claims
- How to prevent your imported entries from being detained for making disease claims
- How to properly write structure/function claims
- How to "qualify" and "limit the scope" of the claim to non-disease states
- The definition of "disease" and the 10 criteria to avoid making disease claims

This webinar is important for marketing and regulatory staff members, as both groups need to understand what claims are permitted by the FDA. Dietary ingredient suppliers, finished dietary supplement

manufacturers, dietary supplement labelers and private-label retailers who construct or adopt structure/function claims for labels or labeling will also want to plan to attend this webinar.

I hope this information is helpful and please let me know if you have any questions.

Best,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org

From: Vicki Whitsitt
Sent: Wednesday, July 30, 2014 8:47 PM
To: Lauren Cohen
Subject: FW: Invitation to speak at a NPA Webinar

Hi Lauren – can you follow up with Dr. dos Santos? Thanks!

From: DosSantos, Mariton [mailto:Mariton.DosSantos@fda.hhs.gov]
Sent: Wednesday, July 30, 2014 3:37 PM
To: Vicki Whitsitt
Subject: RE: Invitation to speak at a NPA Webinar

Hello Vicki,

Sorry for the delay in replying your email. Below is a short bio and attached is the headshot.
Also, could you provide me more information on the webinar? such as: the topic and the duration of the presentation.

Thank you in advance.
-Daniel

Bio:

M. Daniel dos Santos, *PharmD/PhD*
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition, FDA

M. Daniel dos Santos works as an Interdisciplinary Scientist in the Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition (CFSAN) at the FDA. In this position, Dr. Dos Santos reviews and evaluates dietary supplement labeling and claims, such as the 30-day notifications (Structure Function Notification) submitted by the industry. He is also the point of contact for Export Certificates of Free Sale, Small Business Nutrition Labeling Exemption (SBNL), and a member of the New Dietary Ingredient Review Team.

From: Vicki Whitsitt [mailto:vwhitsitt@npainfo.org]
Sent: Wednesday, July 23, 2014 4:47 PM
To: DosSantos, Mariton
Subject: RE: Invitation to speak at a NPA Webinar

Hi Dr. dos Santos:

Hope all is well. We are beginning to put our August 20th webinar announcement together and would like a bio from you, and a head shot if you have one available. Thanks!

Best regards,
Vicki Whitsitt
Director, Scientific and Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
(202) 503-1961
(800) 966-6632 x243
Fax (202) 747-7663
NPAinfo.org

From: DosSantos, Mariton [mailto:Mariton.DosSantos@fda.hhs.gov]
Sent: Monday, July 14, 2014 9:09 AM
To: Vicki Whitsitt
Subject: RE: Invitation to speak at a NPA Webinar

Hi Vicki,

Yes, you can count on me.

Corey Hilmas has suggested Aug 20th. I will be ok for Aug 20… just let me know.

Thanks,
-Daniel

From: Vicki Whitsitt [mailto:vwhitsitt@npainfo.org]
Sent: Thursday, July 10, 2014 2:06 PM
To: DosSantos, Mariton
Subject: RE: Invitation to speak at a NPA Webinar

Dear Dr. dos Santos:

I want to follow up on our invitation to you to speak at our August 13 webinar. Have you received any feedback (or hopefully a green light) to participate? Thanks!

Best regards,
Vicki Whitsitt
Director, Scientific and Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
(202) 503-1961
(800) 966-6632 x243
Fax (202) 747-7663
NPAinfo.org

From: DosSantos, Mariton [mailto:Mariton.DosSantos@fda.hhs.gov]
Sent: Wednesday, June 18, 2014 12:33 PM
To: Vicki Whitsitt
Cc: Christin, Charlotte - OC; Welch, Cara
Subject: RE: Invitation to speak at a NPA Webinar

Dear Vicki,

Thank you for contacting me with the invitation to be a presenter on a NPA webinar - converging dietary supplement immunity claims (Structure Function Claims). I will notify my superior and get back to you as soon as I have her feedback/green light.

By the way, besides Dr. Hilmas, who else will be presenting on the webinar?

Thank you,

-Daniel Santos

M. Daniel dos Santos, *PharmD/PhD*

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Dietary Supplement Programs
5100 Paint Branch Parkway, room 3C-081
College Park, Maryland 20740
e-mail: mariton.dossantos@fda.hhs.gov
Phone: 240-402-2818

From: Vicki Whitsitt [mailto:vwhitsitt@npainfo.org]
Sent: Wednesday, June 18, 2014 2:43 PM
To: DosSantos, Mariton
Subject: Invitation to speak at a NPA Webinar

Dear Dr. Dos Santos:

I hope this finds you well. I have been told that you are the point of contact person for dietary supplement structure function claims, and therefore NPA and Dr. Corey Hilmas would like to invite you to be a presenter on a NPA webinar covering dietary supplement immunity claims. This is a hot button issue for the industry and our members are eager to hear from FDA about this topic. You would be presenting with Dr. Hilmas, NPA's Senior Vice President of Scientific and Regulatory Affairs. We would like to hold the webinar on Wednesday, August 13th, at 2:00 p.m. EDT. NPA can be somewhat flexible about dates and time, and if August 13th or 2:00 p.m. EST doesn't work, please let us know and we can look at other dates or times. Please let me know if you have any questions about the webinar or need additional information to make a decision. Looking forward to hearing from you.

Best regards,
Vicki Whitsitt
Director, Scientific and Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
(202) 503-1961
(800) 966-6632 x243
Fax (202) 747-7663
NPAinfo.org

From: Harry, Molly
To: Welch, Cara
Cc: Strambler, Karen; Assar, Carrie; Honigfort, Mical
Subject: FW: Meeting Request with NPA re: Carrageenan Advisory Committee
Date: Friday, July 01, 2016 11:25:00 AM
Attachments: image003.png
image004.png

Hi Cara,

OFAS has reviewed the safety of food-grade carrageenan extensively and we have no safety issues with its use in food. There are regulations in the CFR permitting the safe use of carrageenan, and available safety data continue to support its safe use. We do not see the need for holding an FAC meeting at this time on this subject. OFAS does not have any questions related to carrageenan that we need to find answers for regulatory purposes. We will be glad to participate in the internal discussion late next week on the subject.

Thanks, Molly

From: Welch, Cara
Sent: Thursday, June 30, 2016 4:59 PM
To: Strambler, Karen
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

I'm comfortable discussing the possibility but (b) (5) . We haven't heard much on Carrageenan from our stakeholders. We can definitely push the discussion to late next week ☺
Thanks for the quick response
Cara

From: Strambler, Karen
Sent: Thursday, June 30, 2016 4:50 PM
To: Welch, Cara
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

Did you want to discuss the possibility of holding a Food Advisory Committee meeting to addressing Carrageenan? If we hold the meeting we could add individuals to the committee, who have expertise on topic. Please let me know how you would like to proceed. I will be out of the office on tomorrow but returning on Wednesday, July 6.

Thanks,
Karen

From: Welch, Cara
Sent: Thursday, June 30, 2016 4:39 PM
To: Strambler, Karen
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie

Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
Molly, Carrie, and I met with NPA on Monday to discuss convening a Food Advisory Committee on Carrageenan. Molly and Carrie are much more knowledgeable on the ingredient (b) (5) . (b) (5) However, JECFA recently confirmed the safety of Carrageenan (I think?) and OFAS as well as Infant Formula seem to be comfortable with Carrageenan in foods/infant formula. I think (b) (5) .

I'm curious Molly, Mical, and Carrie's impressions on the desire/need for an AC on carrageenan.

Thanks
Cara

From: Strambler, Karen
Sent: Thursday, May 19, 2016 3:59 PM
To: Welch, Cara
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

I spoke to Susan Bernard about this and no need include me in the meeting with NPA but we can talk after you meet them.

Thanks.

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:16 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Thanks. Should you be involved in a meeting with NPA?

From: Strambler, Karen
Sent: Thursday, May 19, 2016 9:15 AM
To: Welch, Cara
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Cara,

I think you should meet with NPA to find out what issues they would like an advisory committee to address. We can talk after you meet with them so I can provide you with information on the

advisory committee process.

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:05 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
I have time today to discuss but I don't have anything to discuss…that is, I don't know what their concerns are ☺
If you want to chat, can you give me a call sometime this afternoon? (2-2333)
Thanks
Cara

From: Strambler, Karen
Sent: Thursday, May 19, 2016 8:58 AM
To: Welch, Cara
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

I don't see a problem with forming a subcommittee to address their concerns. Are you available today to discuss this topic?

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 8:49 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: FW: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
OFAS, ONFL, and ODSP were contacted by the Natural Products Association for a meeting request re: Carrageenan. At this point, (b) (5), since I'm not aware of dietary supplement concerns with carrageenan. Since you're the food advisory committee federal officer, I wanted to get your opinion on the request.
Thanks
Cara

From: Michael Kelley [mailto:mkelley@npainfo.org]
Sent: Thursday, May 12, 2016 12:07 PM
To: Assar, Carrie; Mattia, Antonia; Welch, Cara; Mozersky, Robert
Cc: Daniel Fabricant, Ph.D.; Corey Hilmas
Subject: Meeting Request with NPA re: Carrageenan Advisory Committee

Good Afternoon-

Mike Kelley with the NPA here. I hope this email finds you all well.

NPA would like to request a meeting to discuss adding Carrageenan to the list of current FDA Advisory Committees. Could you let me know if there a specific date and time that works for your team in the coming weeks?

Thank you in advance,

Mike

Michael Kelley
Director, Government Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office: (202) 204-4720
Cell: (703) 509-7052
www.NPAinfo.org


From: (b) (6)
To: Welch, Cara
Subject: Fwd: NPA Thursday Roundup
Date: Friday, December 22, 2017 11:18:16 AM

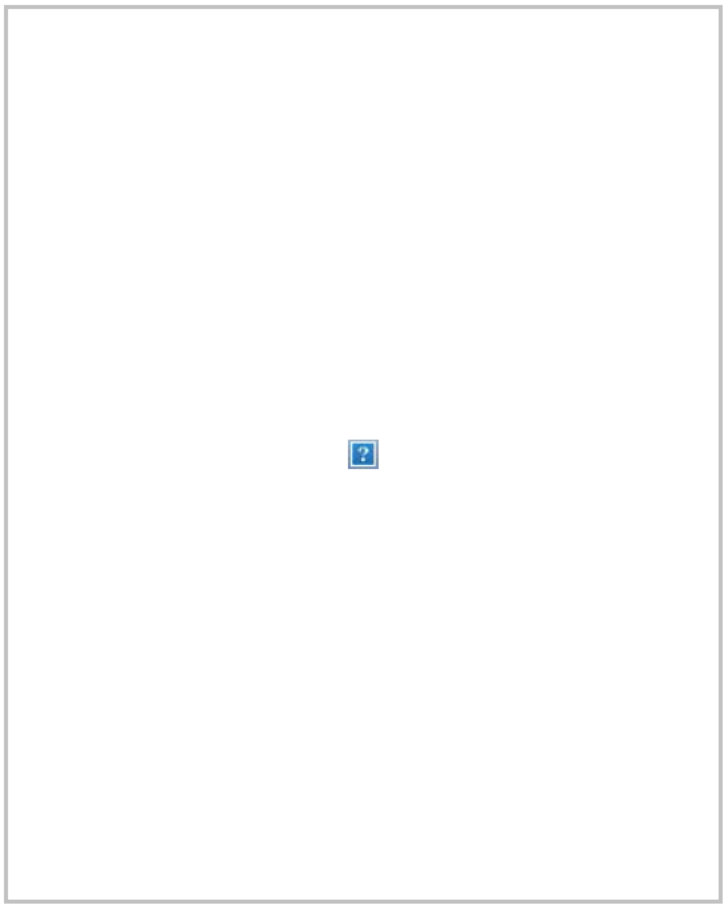
---------- Forwarded message ----------
From: **Dr. Daniel Fabricant** <daniel.fabricant@npanational.org>
Date: Thu, Dec 21, 2017 at 3:59 PM
Subject: NPA Thursday Roundup
To: (b) (6)

View web version

December 21, 2017

NPA Meets with OMB to Discuss the Nutrition and Supplement Facts Labeling Final Rule

Last week, Dr. Fabricant met with OMB to discuss the nutrition and supplement facts labeling final rule. A very important matter given that the industry has to spend $200 million to made label changes. The unduly, burdensome changes seen in the final rule now require dietary fibers firms to do 2 RCTs (Random Clinical Trials) to show a beneficial physiological effect. In addition, the eye tracking studies, designed to support some of the new changes like added sugars, do not support FDA's position in this final rule. Furthermore, the FDA failed to submit an economic impact analysis with the guidance to OMB regarding this new cost burden to the food and supplement industry. If the Agency is implementing such burdensome changes, they must first provide material evidence in the form of substantiated consumer studies, which serves as the basis for the labeling changes. Therefore, NPA is requesting a 3 year extension in the compliance date for the final rule, as it provides sufficient time for the agency to conduct proper empirical studies involving consumer research and will allow for accurate and consistent changes to be made, without crippling costs to business that will be passed on to all American consumers.



NPA and Their Members Are First Again, First Ever Request of Its Kind (Using the IFR on Reduced ID Testing) Submitted on Behalf of Bergstrom Nutrition

A request made on behalf of Bergstrom Nutrition by the Natural Products Association (NPA) to the Food and Drug Administration (FDA) could lead to lower costs for consumers and the federal government and increase the overall quality of nutritional supplements. This is the first time a manufacturer has submitted a Citizen Petition requesting a reduction in identity testing while showing no diminution in product quality, based upon their historical record of demonstrating high quality.

Click here for the news release and the Citizen Petition.

NPA Makes a Statement on NBC's Nightly News Regarding FDA's Draft Guidance on "Drug Products Labeled as Homeopathic"

FDA says it will crack down on homeopathic products. NPA responds.

Click here to watch the video.

Dan Fabricant on Leadership in Action

Dan Fabricant was interviewed on Business Radio's *Leadership in Action* on Sirius XM.

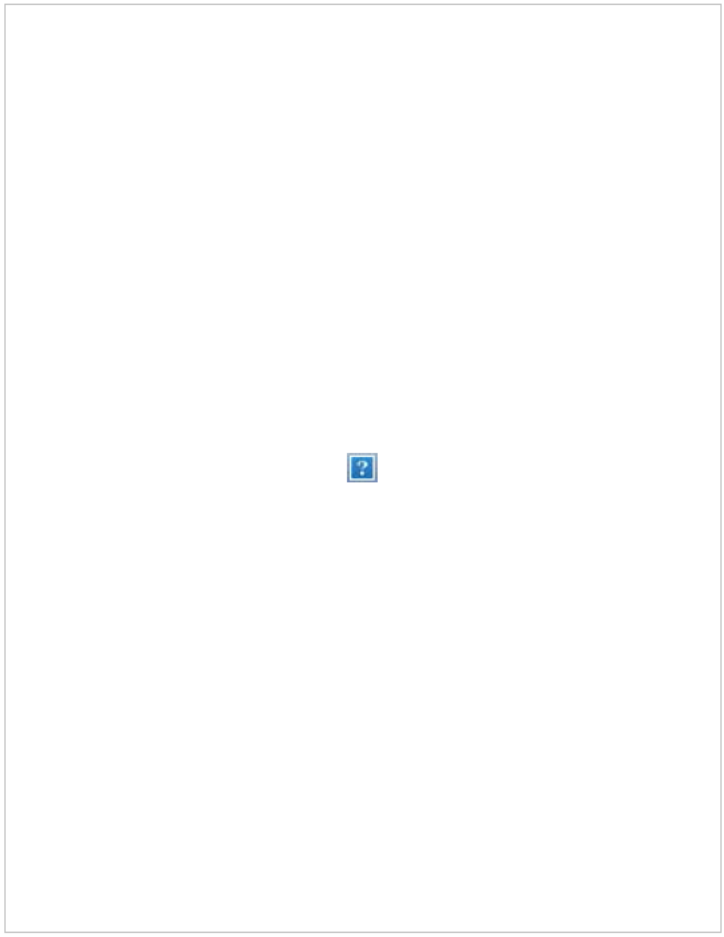
Click here to listen to the interview.

Register for Natural Products Day 2018

Each year, the natural products industry gathers in our nation's capital to educate members of Congress and legislative staff about the important role natural products play in keeping Americans healthy and the overwhelming public benefits of preventive care. This day-long advocacy conference is hosted each year by NPA to provide retailers, suppliers, and all industry stakeholders from across the country with the opportunity to become lobbyists for a day.

There is no registration cost to attend and all meetings will be arranged by NPA.

For questions and registration, email Natural@NPAnational.org



The Natural Products Association Would Like to Welcome Our First Event Partner to the Second Iteration of The Big Natural

We are pleased to be joined by Ronie Schmelz of Tucker Ellis LLP! Ronie will be joining us as a moderator for one of the Government Spotlight Discussions.

Offering 2 days of industry-driven educational sessions, including interactive discussions, case studies and valuable benchmarking and networking opportunities, The Big Natural is the only event that will put you in the same room with industry leaders who are currently driving innovation in the natural products industry. Only a limited number of spaces will be made available for program sponsors in the legal and business innovation track sessions. To learn more about how to get involved as a sponsor, contact Danielle Gonzalez at Danielle@Momentumevents.com.

NPA Pre-DSHEA ODI Book Orders Are Rolling In Reserve Your Copy Today

A new book from NPA compiles the first ever list of pre-DSHEA dietary ingredients. The NPA book, titled Pre-DSHEA List of Old Dietary Ingredients, is available for pre-sale until the end of the year for both members, non-members, federal agencies and non-governmental organizations (NGOs).

“This book is the first of its kind and should serve as a valuable tool for industry regulatory divisions, retailers, industry consultants, as well as state and federal regulators,” said Dan Fabricant, Ph.D., President and CEO of NPA and one of the book’s authors. “NPA continues to work with the FDA in their quest to develop a list of its pre-DSHEA dietary ingredients that are exempt from notification. This book represents a considerable investment of NPA’s resources and took over 2 years to develop. We look forward to releasing new editions of the book as we add new independently verified ingredients to this extensive collection.”

PRE-ORDER YOUR COPY NOW

Tell Congress TODAY to Cosponsor H.R. 3529 - the "WIC Improvement Act"

Representative Dave Brat (R-VA) recently introduced H.R. 3529, the “WIC Improvement Act,” for the inclusion of multivitamins for purchase as part of the special supplemental nutrition program for women, infants, and children (WIC). The WIC program provides Federal grants to States for supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age 5 who are found to be at nutritional risk. The program has grown significantly in its nearly 40-years of existence, and it now serves approximately 8 million participants.

The “WIC Improvement Act” will expand WIC to give these low-income families equal opportunity for access to low-cost, high nutrient alternatives, like multivitamins. Multivitamins are proven to have many health benefits especially relevant to those the WIC program intends to help:

- Classic nutrient deficiency diseases (scurvy, pellagra, and iron deficiency anemia)
- Improve appetite and growth rates
- Prevent neural tube birth defects
- Protect against heart disease and stroke

- Build bone mass in young children

The "WIC Improvement Act" will help provide relief to the 25 million Americans currently living in "food deserts." The United Stated Department of Agriculture (USDA) defines a food desert as: parts of the country vapid of fresh fruit, vegetables, and other healthful whole foods, usually found in impoverished areas. With your support, millions of Americans will be able to provide healthier lives to their families.

Tell your Representative TODAY to cosponsor H.R. 3529.

TAKE ACTION NOW

Stevia Included in Philadelphia Soda Tax

The City of Philadelphia has recently passed the Sugar-Sweetened Beverage Tax or the "Soda Tax," which took effect January 1, 2017. Within this newly enacted legislation, stevia was included as a part of the artificial sugar substitutes that should be taxed. However, as you may know, stevia is a natural plant-derived sweetener and therefore should not be included. Since the tax has been implemented, beverage prices have seen the following increases:

- 20-ounce drink that used to cost $1.99 is now $2.29
- 64-ounce jug of juice at $2.39 is now $3.35
- 6 pack of diet green tea at $4.99 is now $6.07

In the "Soda Tax" all distributors and dealers pay $.015 per ounce of sweetened beverage, and as taxes get added, the cost often gets passed downstream ultimately to the consumer.

Write Frank Breslin, Commissioner of Department of Revenue, TODAY to tell him that stevia should not be included in the Sugar-Sweetened Beverage tax.

TAKE ACTION NOW

Natural Products Association
440 1st Street NW, Suite 520, Washington, DC 20001
Visit our website | Contact Us

From: Newhart, Corinne
To: Tave, Steven; Welch, Cara; Durkin, Robert
Cc: Naum, Marianna; Meyer, Lyndsay
Subject: FYI: NPA urges FDA to move faster to publish list of pre-DSHEA dietary ingredients
Date: Wednesday, August 23, 2017 3:07:37 PM

NPA urges FDA to move faster to publish list of pre-DSHEA dietary ingredients

This article is powered by Food Chemical News
21 Aug 2017
NEWS

Ingrid Mezo ingrid.mezo@informa.com

FDA is dragging its feet on putting out a list of pre-Dietary Supplement Health and Education Act (DSHEA) dietary ingredients that would not require a 75-day premarket notification filing with the agency, the Natural Products Association (NPA) said.

Under DSHEA, the manufacturer or distributor must notify FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (NDI) – one that was not marketed in the U.S. before Oct. 15, 1994 – unless the NDI is used in the food supply without chemical alteration. Dietary supplements that do not meet these conditions are considered adulterated.

Dietary ingredients marketed in the U.S. before Oct. 15, 1994 are "grandfathered" in under DSHEA. These ingredients are considered to be safe for continued consumer use and can be sold without prior notification to FDA.

NPA wants FDA to move swiftly to publish a list of these grandfathered ingredients so that dietary supplements manufacturers can have more certainty in the

marketplace.

While NPA said the agency will be holding an Oct. 3 public meeting to discuss the development of a list of pre-DSHEA dietary ingredients, NPA wants the agency to do more than just talk about the list and would prefer to meet with FDA before October.

In April, NPA asked to share with the agency a preliminary list NPA compiled of more than 2,000 pre-DSHEA dietary ingredients based on historical information from food retailers, including independent, verifiable evidence in the form of ads in catalogs and bills of lading.

NPA is confident the list would meet FDA's standards for "independent and verifiable" discussed in the draft guidance on new dietary ingredients published in August 2016.

'No clear reason' for delay

But "for no clear reason" the agency has delayed NPA from sharing that information with them and establishing a pre-DSHEA list, Dan Fabricant, executive director and CEO of NPA, told *IEG Policy*.

NPA noted that FDA does not have clear statutory or regulatory authority to establish a pre-DSHEA list, and is, therefore, establishing such a list on its own discretion.

"Given that there's not a statute here, there's not a reg here, the agency is going to have to be flexible, and if someone can come in and show them a couple thousand ingredients that were clearly on the market pre-1994, why would you wait six months to have a meeting, basically a presentation versus any progress for six months?" Fabricant asked.

FDA previously said it would not accept an industry-created list of acceptable pre-DSHEA dietary ingredients and that it would need to develop its own list of these ingredients.

“The old lists that industry had were just lists,” Fabricant explained. “They didn’t have anything behind them. We have publications behind ours that clearly meet the independent verifiable standard, that has catalogue advertisements, bills of lading, things like that. That’s the type of data they want and that’s what we have, and we want to go in there and show them that, but it’s copyrighted, so we don’t just want everyone to have access to it, but at the same time we have evidence so that FDA can develop [their own] list and they’re stalling.”

NPA has also been highly critical of FDA’s revised new dietary ingredient notification guidance released in August 2016. NPA, among other complaints, said FDA’s testing recommendations in the revised draft continues to blur the distinction between dietary supplements and conventional food ingredients in FDA’s testing recommendations.

When FDA released the draft guidance, the agency estimated that more than 55,600 dietary supplements were on the market, and that 5,560 new dietary supplement products come on the market each year – in contrast to the approximately 4,000 products that were on the market in 1994. But the agency said it has received fewer than 1,000 NDI notifications since DSHEA was passed in 1994.

‘Take another bite at the apple’

NPA has separately pushed FDA to not just delay the agency’s Nutrition Facts label rule, but to withdraw it, citing the rule’s inconsistency with the new administration’s regulatory agenda, as well as serious First Amendment issues.

The rule includes a Daily Value (DV) for added sugars that was not in the proposed

rule, is inconsistent with the findings of its own consumer studies, is not supported by eye-tracking studies and includes an “unjustified” new definition of dietary fibers, NPA said in a June petition to the agency.

After FDA in June indefinitely delayed the original July 2018compliance withthe Nutrition Facts rule, FDA Commissioner Scott Gottlieb assured a Senate subcommittee that the agency has no plans to reopen the rule to changes.

Fabricant said it would make sense for the agency to delay the compliance with the rule until 2021, and urged the agency to “take another bite at the apple and reopen those comment periods with respect to fiber, sugar, salt and some other areas.”

From: NutraIngredients-USA
To: Welch, Cara
Subject: Kratom: Is the DEA waivering? / NPA requests vinpocetine comment extension / Another krill patent lawsuit / Coromega bioavailability / POS expands into the US / SSW Education
Date: Wednesday, October 05, 2016 11:15:42 AM

If you are unable to view this message correctly, click here

Visit the NutraIngredients-USA team at Supply Side West, Booth I-164, October 4-8

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05-Oct-2016

DATA SHEET

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NPA requests one-year extension to vinpocetine comment period

Sacco

The Natural Products Association has called on the US Food and Drug Administration to extend the comment period on the status of vinpocetine until September 6, 2017. .. Read

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Litigation in the krill sphere continues to proliferate, with a new suit from Aker BioMarine against Chinese firm Luhua BioMarine. .. Read

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Why Health Canada's proposed overhaul of NHP regs are a concern to the industry

Health Canada is proposing to significantly change how natural health products and dietary supplements are regulated, with industry sources telling us the proposals are a concern... Read

October new product launches: Energy drinks and soothing teas

What's new in dietary supplements this month? A new line of RTD energy drinks by BluePrint, powered by tea ingredients like yerba mate, matcha, and guayusa, as well as a calming tea formulated for tranquility made out of tulsi. Other additions include a children's cognitive performance supplement and halal multivitamin gumies for children... Display

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Veteran snack-maker Two Moms in the Raw expands its portfolio of organic plant-based products after rebranding as Soul Sprout to appeal to more consumers and better communicate the added-value of its food as well as more firmly ground the company's image in nutritional science... Read

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- **A Deep Dive on Krill Oil Concentrate** - Aker BioMarine
- **Build A Weight Loss Brand Consumers Can Trust** - PLT Health Solutions

From:	eva
Subject:	LETTER FROM JARROW ROGOVIN TO NPA"S ACTING COO AND MEMBERS OF THE BOARD
Date:	Wednesday, September 17, 2014 11:40:56 AM
Attachments:	EA NPA LTR 9 16 2014.pdf EA NPA Ltr Attachments 9 2014.pdf
Importance:	High

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Via U.S. Mail and Emails

Current Acting COO and
Members of the Board
Natural Products Association
1773 T Street, NW
Washington, DC 20009

September 16, 2014

Re: Dr. Fabricant, Dr. Hilmas:
Conflict of Interest;
False Advertising;
Federal Lobbying Restrictions (Fines up to $50,000 each); and
Current state of NPA

Dear Members of the Board and Acting COO:

I wrote the NPA Board a detailed letter on April 29, 2014 about various conflicts of interest and issues affecting the public perception of the Dietary Supplement Industry arising out of the re-employment of Daniel Fabricant, this time as NPA's Executive Director. In light of additional information, further turnover at NPA and the failure of the NPA's Board to respond to date, this is to review and expand on my earlier comments.

It is astounding that the NPA Board hired Dr. Fabricant after he had apparently worn out his welcome at CFSAN by being an attack dog against the supplement industry and, in addition, creating a sufficiently hostile workplace that a lawsuit was filed by one of the scientists working under him. His "separation" from the Agency occurred shortly following receipt of Jarrow's March 4, 2014, 90-item FOIA, which also was copied to Commissioner Hamburg, and the filing of an employment suit against HHS naming Fabricant as the culpable party.

It was then further unexpected that this Board--in particular, the Executive Committee of NPA – hired Dr. Corey Hilmas, the second in command "Team Leader" in the Office of Dietary Supplement Programs, to be Fabricant's lieutenant at NPA. For many reasons FDA should not have hired Dr. Fabricant nor Dr. Hilmas into supervisory positions. Likewise, the NPA should not have hired the pair to "represent" the supplement industry. As I will detail below, the very FDA background that NPA finds so valuable is the factor that legally renders Fabricant and Hilmas nearly useless as advocates and lobbyists since both federal statute and federal regulation prohibit their post-employment activities for two years after their departure from the Agency. Statutes aside, their clear FDA-era record – virulent and non-stop criticism of the supplement industry in overt collusion

with media nationwide and anti-DSHEA provisions in the Draft NDI Guidance often involving obvious misrepresentations and a skewing of facts and figures, makes NPA's hiring of the duo unfathomable and objectionable.

1. We only can assume that while he was Director of Dietary Supplement Programs, Dr. Fabricant demonstrated the same arrogant, offensive, dismissive, and generally unprofessional behavior to his subordinates that he indulged in at various webinars and convention presentations. Dr. Fabricant's term in office seems to have resulted in other high-level enforcement and policy officials leaving the DS office. Exhibit "A" of the problems caused within the agency by Dr. Fabricant was a lawsuit filed by Dr. Kenneth Taylor: *Taylor v. Sebelius* (now Burwell), No. 13-cv-1998, U.S. District Court, District of Maryland, in which Dr. Kenneth Taylor (formerly reporting to Fabricant) alleges EEO claims including age discrimination, a hostile workplace environment, and retaliation. Although the first two claims above have been dismissed, the claim of retaliation by Fabricant for Dr. Taylor filing an EEO claim is at issue. The Complaint and its attached affidavits paint a detailed and unpleasant picture of the workplace atmosphere and mismanagement during the regime of Fabricant in the Office of Dietary Supplement Programs. Among other mismanagement issues, Fabricant assigned high level Ph.D. scientists to menial clerical work such as issuing Certificates of Free Sale for exporters. This was a gross waste of taxpayer money, an abuse of employees, and caused misdirection and mismanagement within the agency which continues to plague it to this day. The legacy of Dr. Fabricant's time at the FDA's DS division's helm is slander and libel of the industry, and chaos, alienation and demoralization within. (See Complaint and Affidavits attached.)

   The individuals who have left the FDA under circumstances that are arguably connected to Dr. Fabricant's term are Dr. Kenneth Taylor due to the work environment, and then Dr. Hilmas and Dr. Barbara Schneeman. Other individuals it seems were unhappy and professionally dismayed during Fabricant's regime. (See the Affidavits attached to the Taylor lawsuit.) I assume that Jarrow's March 4, 2014 FOIA to the FDA re Dr. Fabricant, which we copied to the top echelon of HHS – coupled with Dr. Taylor's lawsuit – caught the attention of some of HHS's top brass. The announced leave-taking relative to the receipt of our FOIA, frankly, reeks of high level intervention. While we are considering another (brief) FOIA in this regard, the NPA board would be justified in asking Dr. Fabricant whether, in the period between early March and late April, 2014, he had any high level meetings about his job performance – if not serious issues regarding his conduct, both publicly and in the ODS. Additionally, was he in effect asked to quietly resign? A review of the wreckage, including his trade show tirades, leads me to believe this was the case. In fact, there were several phone calls that lead us to believe such high level meetings were occurring. We were informed by trade press that Dr. Fabricant might be leaving FDA. One of Jarrow's representatives then attempted to call his office, and was told that Dr. Fabricant was in meetings. After additional calls to members of the industry, we assumed that "might be leaving" was definite (i.e., "would be leaving"), that his superiors could not ignore the situation(s).

   The agency had radically extended itself in hiring the VP of Scientific and Regulatory Affairs and past-Acting Executive Director of NPA, a high-profile trade association. Subsequently, that hiree radically extended himself making outrageous public statements and repeated boorish public behavior. The strident anti-industry attacks had not created such an adversarial relationship since the term of Dr. David Kessler as Commissioner in the early and mid 1990's. If that is not enough, Jarrow utilized the FOIA Act to hold the agency factually accountable for the reckless rampage of its self-promoting Director of Dietary Supplement Programs. Suddenly, after three years, the agency was being held responsible, legally and factually, for Dr. Fabricant's unprofessional, unethical and untruthful

campaigning. The fact that Senator McCain's office weighed in with the agency on Jarrow's FOIA certainly would have reached higher ups. Accordingly, I have reason to believe that a major higher-up "invited" Dr. Fabricant to his or her office to discuss "problems" and "suggested resignation."

As citizens, participants in the affected industry and leaders in the trade association of concern, how matters resolved between Dr. Fabricant and the agency are not matters of "personal concerns." These questions are of concern to the industry and the public and the circumstances under which that particular executive left his last employment absolutely begs public hearing: Which HHS executives did Fabricant talk to his final month, and what were the contents of those conversations? Did it stop with Dr. Michael Landa? Did it go as far as Commissioner Dr. Margaret Hamburg herself? Now imagine you are one of the reporters from *USA Today, Chicago Tribune, New York Times, NBC Dateline*, NPR radio – or even the *Time Magazine* reporter who wrote that bit of hagiography (about "The King of Natural Food [sic] Takes Some Questions.") – and get the rest of the story. The Real Story! Stop the cover up. It becomes its own scandal.

2. Dr. Fabricant's original move from NPA to FDA was an ethical breach, a classic conflict of interest by both Fabricant and the Agency. Companies and their counsel, as well as the public, need to be able to exchange information and legal analyses and strategies freely without concern that the confidentiality and integrity of the information might be compromised by some future errant trade association executive suddenly in concert with the regulating agency. Undeniably, the offer and acceptance of his employment at FDA resulted in Dr. Fabricant not only abrogating his previous fiduciary position, but also actually violating the previous attorney-client relationship since he was present at and engaged in numerous conversations and exchanges with the NPA's attorneys. The hiring of Dr. Daniel Fabricant by the agency and then again by the NPA has left unresolved the irreconcilable opposing positions taken by Dr. Fabricant before and after his FDA appointment.

3. During his 3 years with the FDA, in an appalling and sudden about-face from his stance while at NPA, Fabricant unleashed a torrent of negative, indeed malicious and slanderous statements about the industry to both the trade press and the mainstream press, including *The New York Times, The Chicago Tribune, and USA Today*—for example:

    - "Half the companies are falling on their faces"
    - "This industry is downright scary"
    - The industry is 70% not in compliance

    To remind the Board, the industry was shocked and then angered by Dr. Fabricant's abrupt transformation into a self-righteous accuser: From defender of the supplement industry in the years 2006 through 2010 in his first stint at NPA to an Agency head using every opportunity to disparage the industry. We are now witnessing his second *volte face*, his *second* reincarnation. There is a credibility gap here, isn't there?

    Dr. Fabricant's theme as DDSP (Director of Dietary Supplement Programs) unfortunately repeated and expanded by a misinformed media, was blanket condemnation of the majority of reputable supplement manufacturers for the sins of peddlers and users of steroids—which in fact are drugs, not supplements. While at FDA, Dr. Fabricant never bothered to emphasize this important distinction as it did not suit his purposes at the time.

    Indeed, it remains, officially, unanswered: Was the agenda Dr. Fabricant's or the agency's? This question, the NPA Board has failed and refused to follow up on. Nor did Dr. Fabricant during his FDA regime articulate the fact that supplements are far safer than virtually all

other FDA-regulated products, including prescription and OTC drugs, medical devices and even conventional foods (given that foodborne illness kills 3,000 to 5,000 Americans annually). That disclosure would not have fit his agenda at that time either. He instead embarked on an *unauthorized* anti-supplement road show, at the same time feeding the mainstream media skewed "facts" and figures, and attention-getting one-liners to support his smear campaign.

Dr. Fabricant himself was repeatedly ***not in compliance*** with FDA rules requiring *pre-authorization and permission* by the agency's Public Affairs Office for giving interviews with the news media. This alone could have been a firable offense and he committed it repeatedly – all to our industry's detriment.

In one particularly maliciously false and misleading instance, Fabricant, in his 2012 remarks about the 2008 "Total Body" case, abetted a slanderous episode of Dateline-NBC's portrayal of supplements in omitting the crucial fact that the vast majority of analytical labs and manufacturers in the industry are highly ethical and reliable, and worse, *covered up that the FDA itself failed to take any regulatory action whatsoever, not even against the Atlas "analytical" lab that committed fraud again and again*. First, he abetted the deliberate deception that the Total Body incident was supposedly recent and a cause for current public concern rather than a four-year old closed case. That was the first of many lies in that episode he facilitated.

Rather than tape Dr. Fabricant in his actual office, and in order to portray FDA's alleged lack of resources, *Dateline* and Fabricant staged the interview of Fabricant seated at a cluttered little work cubicle (against a wall in a room adjacent to his own spacious, well-furnished and windowed office), with creepy (horror movie) background music to suggest an ominous situation. Fabricant abetted – if not designed – *Dateline*'s viciously anti-supplement industry harangue. In his episode, he falsely attributed FDA's failure to take action against Atlas Labs to a lack of resources to conduct GLP audits. Atlas Labs was an OCI, Office of Criminal Investigation matter that should have been referred for prosecution but wasn't. Yes, there were private company failures: But the failure and cover up by the FDA – compounded by horrendous public defamation of an entire industry four years later--was scandalous and displayed a form of official corruption.

In addition to giving more than one interview to the reporter Trine Tsouderos, he collaborated with and supplied the sensational headline *"FDA: Supplements Downright Scary"* for a July 1, 2012 cover article in *The Chicago Tribune*. This article includes Dr. Fabricant's infamous remark that at least one-half of supplement companies are "falling on their face," an untruth that provided fodder for fresh calls for more Draconian anti-supplement legislation by Senators Durbin and Blumenthal and other long-time industry foes. These attacks were heavily reported and required the industry to expend considerable resources to marshal a defense. Has the NPA Board forgotten the exigencies created by Durbin when he struck out against the industry in coordination with stories planted in the press by Dr. Fabricant?

Without any credible basis, FDA inflated the non-compliance figure in an offhand remark that appears in a later (November 5, 2013) *New York Times* article, *"Herbal Supplements Often Are Not What They Seem."* Reporting on DNA barcoding of dietary supplements by Canadian researchers, FDA spokesperson Shelly Burgess asserted that approximately **70%** of dietary supplements are in "non-compliance," a figure that Dr. Fabricant later literally bragged came "from us." At the same time, despite the explicit legal framework in DSHEA, and a total of at least 18 regulations governing supplements, the article repeats the oft-stated criticism that supplements are part of the unregulated "Wild West." Neither the author of the article nor the FDA spokesperson explains the obvious contradiction: How can a supposedly unregulated industry be in "non-compliance"? The American Herbal Products

Association (AHPA) and many others in the dietary supplement industry vigorously rebutted the flaws in the careless extrapolations and assumptions made from the barcoding studies presented in *The New York Times* article. Dr. Fabricant stuck to his party line.

On November 7, 2013, two days after publication of the article above, a National Public Radio (NPR) program, running with the barcoding article, interviewed Dr. Fabricant who made statements defending the barcoding study. The radio interviewer quotes the statistic of 70% non-compliance in *The New York Times* article. Dr. Fabricant replies: "Yeah. *And they got that statistic from us*." (Emphasis added.) This 70% statistic is, of course, significantly higher than Dr. Fabricant's "50%" non-compliance number he gave for earlier – unauthorized – articles, e.g., re GMP enforcement. In essence, it is the inflation of an already inflated number.[1]

Also, during this radio program, Dr. Fabricant states: "I think people look at a capsule, they look at a tablet, they think this is a medicine. Like what they get from the doctor that goes through FDA approval [for] safety and efficacy." [Emphasis added.] This is a reprehensibly irresponsible statement from the former Vice-President of Scientific and Regulatory Affairs and Acting Executive Director of the Natural Products Association, now chosen to lead NPA once again. How can this reincarnated Executive Director walk back this damning statement, which implants in consumer's minds the notion that supplements are drugs?

Many later news articles further repeated unsubstantiated figures supplied by Fabricant and his lieutenants at FDA and others – including Dr. Paul Offit, hardly an expert on nutrition science, and an opportunistic self-promoter of his recent book, "*Do You Believe in Magic?* In one such article, the scathing December 14, 2013 *New York Times* anti-supplement diatribe "*Skip the Supplements*," Offit, with co-author Sarah Erush, asserted that many supplement companies, when questioned, "lied; they said they met GMP standards but *calls to the F.D.A.* revealed they had been fined for violations *numerous times*." [Emphasis added.] Yet there never was any substantiation for these impossible assertions, or repudiation by Dr. Fabricant. This is the man who is now chosen to promote the supplement cause for NPA *and its members* and by context the rest of the industry?

4. Now that the top two officials of the Division of Dietary Supplement Programs are the top two executives at NPA, it is unsurprising that the various announcements and notices for talks to be given by Fabricant and Hilmas contain hyperbole and otherwise distort the realities, e.g., in plans for Supply Side West in October 2014. (See notices and advertisements attached.) Ironically, over the years, NPA has touted its "Truth in Advertising" program for self-policing of supplement product marketing, while the trade association itself is indulging in false advertising.

   One deceptive example is the ad with the tag line "The Doctor is In," promoting Dr. Corey Hilmas, MD. (Attached.) Our research shows that he is not licensed as a practicing physician in D.C., or Maryland, or Virginia, or indeed in any of the 50 states. He has the degree but we can find no record of his being Board Certified to practice medicine, so the doctor cannot be "In." Furthermore, our research has revealed that the biography posted by Dr. Corey Hilmas on LinkedIn – is likely padded and embellished, in numerous particulars. See examples below. The NPA appears to be engaging in some rather inaccurate advertising.

   The "self-advertising" of Corey Hilmas is also questionable. We have carefully reviewed his LinkedIn Profile—which is created by and self-posted by the subject; and our investigation revealed the following aggrandizements and discrepancies:

   - His education section indicates Harvard University School of Government.

However, we believe that was merely a 1-2 week course that he attended (at the suggestion of Dr. Fabricant?). But, of course, Harvard sounds more glamorous than University of Maryland where he attained his graduate degrees.

- Dr. Hilmas calls his title at FDA “Branch Chief," but he was not. First, he was a scientist and M.D. He appears to have been detailed as acting Team Leader for the Dietary Supplement Regulation Team. (See the Affidavits attached to the Taylor Lawsuit).

- Dr. Hilmas may not have really worked in the capacity of Team Leader and assign work in the normal sense. Rather, Fabricant was the direct supervisor for those individuals for a significant part of that time and signed the performance appraisals and approved leaves and timecards. Dr. Hilmas’ “Team” consisted of only 3 or 4 people, with the primary work actually being managed and supervised by Dr. Kenneth Taylor.

- In September 2012, our information is that Fabricant arranged for a GS-15 announcement for Dr. Hilmas. According to the announcements, one of the requirements for the position was that applicants would need to have at least 12 months prior relevant experience on the date the job announcement closed, which was in September. Based on the information contained in the Taylor lawsuit, Hilmas may not have met the requirements in terms of performing certain duties for the specified time. However, he was promoted nonetheless.

- The Federal Expert Witness credential seems a bit of puffery, as our information shows that he provided testimony in just one case.

- The merit award at CFSAN could be merely, and seems likely was, a Fabricant nomination, precisely intended to pad the resume.

- Contrary to the LinkedIn Profile, Dr. Hilmas was not a co-author on the liquid dietary supplements guidance. That would have been physically impossible: the original draft guidance on liquid supplements/ beverages was issued before Fabricant began at CFSAN; and to our knowledge, Dr. Hilmas had not been assigned to work on that project.

- Finally, we are skeptical of any representation that Dr. Hilmas was a co-author on the NDI Draft Guidance, which was mostly written by Bill Frankos, and which was approximately 3/4 completed as of March 2011, by Dr. Fabricant’s own report, 4 short months before this lengthy document (75 pages single- spaced) was officially issued on July 5, 2011.

5. These industry event notices advertising the Fabricant/ Hilmas talks promise “inside” information about FDA internal policy, etc. However, imparting such information from the agency they so recently left is most probably in violation of a federal statute and a federal regulation. In particular, the statute 18 U.S.C.A. § 207 – Restrictions on former officers, employees, and elected officials of the executive and legislative branches, especially section (c) – which references a 2-year cooling off period. See also the regulation 5 C.F.R. § 2641 – Post-Employment Conflict of Interest Restrictions. The FDA provides information on post-employment restrictions on its website at http://www.fda.gov/AboutFDA/Ethics-Post with links to the Department of Health and Human Services’ *Summary of Employment Restrictions* and the Office of Government Ethics’ *Rules for the Road*. Also, in addition to the FDA

restrictions, the OGE Rules is an HHS Summary. Links are: http://www.oge.gov/Rules-for-the-Road/ and http://www.fda.gov/SummaryPost Empl Restr.pdf. The bottom lines are these ads are false and deceptive.

6. Drs. Fabricant and Hilmas were both high-level officials. And thus, pursuant to the same statutes they are precluded from appearing before the FDA or any government body, including Congress, for a cooling off period of two years since their separation from the agency. This first restrictive statute, 5 C.F.R. §2641, would be quite inclusive for Dr. Fabricant and Dr. Hilmas and would restrict their communications not only on matters which either former employee had responsibility for, but also on matters which they delegated to an underling or subordinate. Since the "actually pending" requirement does not have a timing restriction and would include any assignment under consideration by any other employee supervised by Drs. Fabricant or Hilmas, almost anything under consideration by either former employee's department or division within the FDA would be off-limits.

   This means that they are:

   A. Forbidden to appear before the FDA on behalf of any NPA member;

   B. Precluded from meeting with FDA on behalf of the NPA organization, including at potential joint meetings before the agency with other trade associations such as AHPA, CRN, ABC, IPA, etc.; and

   C. Prohibited by law from appearing before any Congressional body (e.g., before a Senate Hearing), on behalf of the supplement industry (NPA or any member).

   Note that Dr. Fabricant has already violated the aspect in C above when he:

   1. Participated in NPA's Lobby Day [indeed on April 8, his first day on the job with NPA]; and

   2. Testified before Congress in the Dr. Oz hearings on false weight loss ads before the Senate Hearing.

7. NPA has hired two senior level officials whose hands are legally tied for two years – barred from performing the advocacy/ lobbying for which the NPA presumably found them attractive. The fine for each improper lobbying violation evidenced can be $50,000 or greater. As two specific examples:

   A. For the next 2 years, Fabricant and Hilmas are both forbidden to appear before the FDA on any aspect of the NDI Guidance—clearly the most important regulatory and policy issue facing the supplement industry in the near future.

   B. For the next 2 years, Fabricant and Hilmas are both forbidden to lobby before any Congressional figure, on GMPs, supplement safety, imports, recalls, supplement advertising, or any aspect of DSHEA which they dealt with at FDA.

   The statute governing the penalties for violation of 18 U.S.C. §207 is 18 USC §216:

   > (a) The punishment for an offense under section 203, 204, 205, 207, 208, or 209 of this title is the following:
   >
   > (1) Whoever engages in the conduct constituting the offense shall be imprisoned for not more than one year or fined in the amount set forth in this title, or both. [All emphases added.]

(2) Whoever willfully engages in the conduct constituting the offense shall be imprisoned for not more than five years or fined in the amount set forth in this title, or both.

In summary, the procedure and penalties for such improper lobbying is as follows: Essentially, the Attorney General (through the Assistant Attorney General) can bring an action in U.S. District Court for a violation of the post-employment restrictions of former federal employees. The process begins with the Assistant Attorney General serving the former federal employee with a written copy of the violation(s), either personally or by registered mail. The former federal employee then has 30 days to show cause why he or she should not be prohibited from the wrongful conduct. The former employee can then either request a hearing or submit an answer and not ask for a hearing. If a hearing is requested, it will occur within a reasonable period of time. If no hearing is requested (or if no answer is submitted) the Assistant Attorney General will forward the record, including the report of the investigation, to the Attorney General for appropriate action. A failure to answer constitutes a waiver of defense.

If a hearing occurs and there is sufficient proof or if a default occurs and no hearing is held, the former federal employee can be subject to *a $50,000 fine for each violation*, or the amount of the compensation received or offered for the prohibited conduct, whichever is greater. The evidence against the former employee must be "substantial." An injunction and criminal penalties are also appropriate remedies, depending on the circumstances and just because one method is utilized, doesn't mean a combination of civil, criminal or injunction is disallowed. After entering the initial decision, either party has 30 days to appeal. If an appeal occurs, the Attorney General reviews the record and makes a final decision to accept, modify or reverse the initial decision.

8. Even if Dr. Fabricant is now portraying himself as an advocate for the dietary supplement industry, a vocal critic of the industry such as Dr. Pieter Cohen or Dr. Paul Offit, or a knowledgeable moderator or reporter, can easily point to any one of the negative statements above to discredit Fabricant's now positive stance[2]. How can Dr. Fabricant maintain credibility as a supplement advocate after three years of pummeling this industry, and all the specific harshly negative and wildly untruthful statements summarized above?

9. More recently, there is a question of further mismanagement of the NPA and continued turmoil evidenced by yet another "dramatic" event – the abrupt announcement by Dr. Fabricant that Devon Powell, COO for less than 8 weeks, has departed. Mr. Powell is known to be a competent, well-respected professional in our industry, who had served admirably in a similar position for AHPA for several years. Is the NPA so soon again having serious management issues? Perhaps NPA's board members who are also CRN board members can ask CRN what the organization should do…

10. There was another example of what I consider impropriety from Dr. Fabricant. When this letter was nearing completion last month, my assistant Eva Alejandrino wrote a polite email to Laura Cohen of NPA requesting the names and email addresses of the Board members, in order to send them my letter in the most convenient way. The request was forwarded by Ms. Cohen to Dr. Fabricant whose response I interpret as Fabricant actually and improperly sequestering knowledge from the board, attempting to control and manipulate the flow of information and discussion. Fabricant works for the NPA board – supposedly – and not vice versa. I consider his email of August 11, 2014, to be out of line.

Hello Eva-

I hope you're well. **We don't give out our Board members or any association members contact information to non-members of the association**. [Emphasis added.] Furthermore, some of the prior correspondence upset some of them so if there is a specific point Mr. Rogovin would like to discuss about NPA I would be happy to have that discussion with him.

Best,
Daniel (See relevant e-mail correspondence attached.)

I also have no wish to discuss anything with Dr. Fabricant. For one, his unprofessional outburst on Skype during his "appearance" before the IPA (International Probiotics Association) World Conference two years ago with nearly 200 people in attendance was all the "personal" communication I tolerated for the last time from him. His performance that day was of a piece with his repeated rants at trade associations. His outrageously high-handed, angry eruption that day upset and left aghast a room full of scientists, academics and business executives. He had received a list of questions from the IPA's board regarding probiotics by email before his scheduled appearance – which for personal reasons he did by Skype at the last minute. He did not address any of the questions asked—issues of central importance to a large segment of the supplement industry. When, on behalf of IPA, the Executive Director and then myself attempted to read the questions, he purposely talked over us, virtually shouting and merely repeating irrelevant non-sequiturs in order to cut off any dialog with this respected international trade association – and then announced that he "had to go." This is NPA's new Executive Director. Congratulations.

As to the above email, Daniel Fabricant is mistaken if he thinks I have any wish to discuss anything with him. He will never again be in government; and whether the NPA board is aware of it or will admit it, many executives in the DS industry are dismayed or confounded over NPA's ratification of three years of having our industry subjected to intimidation by a public official, including trade slander, and a generalized threat against our businesses. No, I will not speak with Dr. Fabricant; and he is instructed to make no attempt to speak with me.

Further, the NPA certainly does give out email addresses of board members to non-members. His claim may sound plausible, but it's rubbish. There is no "point…[I] would like to discuss about NPA" with him. It is NPA's Board that needs to have its own discussion with Dr. Fabricant about his betrayal of the industry while at FDA, his workplace insulting tone, hostile atmosphere, and mismanagement at FDA, and the fact that many in the industry and the FDA do not share the NPA's Executive Board's seemingly high opinion of his work history or public record. The NPA should also consider that the survivors at FDA's Office of DS Programs likely want nothing to do with him.

Conclusion:

Dr. Fabricant's negative, alarmist, toxic comments about the supplement industry were quoted and expanded by the news media – e.g., in the *Chicago Tribune*, the *NY Times*, and *NPR*. This damage to the industry went on for three years – somewhat rebutted by the trade associations -- though least and weakest of all by NPA. Dr. Fabricant's negative campaign seemed designed to actually cause a **reduction** of the supplement industry – reduction of sales, of safety image, reduction of the introduction of new ingredients and innovative supplements, and most importantly, the reduction of consumer confidence in supplements. Dr. Fabricant tarring the industry is his legacy, and the NPA has done nothing to repair this damage, as it has put itself in the position of being unable to repudiate any news outlet that challenges the NPA with quotes from its own leadership.

With NPA's hiring of Dr. Fabricant as Executive Director and CEO – an action that seems incomprehensibly irrational -- NPA has a responsibility to account for Fabricant's slanderous statements to and about the industry. Instead, NPA seems more concerned with advertising itself under false pretenses rather than setting the record straight and protecting our industry.

Further, even if Daniel Fabricant changes stripes (again) and somehow advocates for the supplement industry:

A. He cannot meet with the FDA for two years, and for some issues perpetually;

B. He cannot appear before Congress or any governmental body as lobbyist or advocate for two years; and

C. The damage has been done in the public's perception about supplements, and some of that image is irrevocable. It is also damage that can be raised again and again.

Social science research and business studies show that bad or negative news or information is much more impressionable and permanent than good or positive information, and also that it takes five to six positive news articles to counteract one negative article. An article entitled "Bad Is Stronger Than Good" concludes that:

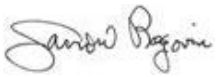
> Bad emotions, bad parents, and bad feedback have more impact than good ones, and bad information is processed more thoroughly than good. [. . .] Bad impressions and bad stereotypes are quicker to form and more resistant to disconfirmation than good ones. [. . . .] Taken together, these findings suggest that bad [press] is stronger than good [press], as a general principle across a broad range of psychological phenomena. [Emphasis added.]

Baumester, Bratslavsky, et al. "Bad Is Stronger Than Good," in Rev of Gen Psychology, 2001, Vol. 5, No. 4, 323-370. Furthermore, it takes several positive articles, quotations, or pieces of news to counteract negative ones, specifically in a ratio of 5.6 to 1. This conclusion is that of the authors of a study published in American Behavioral Scientist. Losada, Marcial and Emily Heaphy, University of Michigan Business School. "The Role of Positivity and Connectivity in the Performance of Business Teams: A Nonlinear Dynamics Model." *American Behavioral Scientist*, 47 (6), p. 740 (2004). With this ratio, it would take 17 years of more positive – and scientifically and statistically accurate – news about dietary supplements to correct the damage that Daniel Fabricant has done to the industry in terms of fomenting negative news and stereotypes for the past 3 years. I'm optimistic, however, that it will take less time to repair the damage. I'm pessimistic that NPA will have any substantial or meaningful role in that process.

Nevertheless, I am repeating my request from April 29 for an open and public accounting by this Board to the Dietary Supplement Industry. My March 4, 2014 90-item FOIA regarding Dr. Fabricant's 3-year reign of error needs to be addressed. Is there a brave soul in the room?

Last point to ponder: Assuming – against federal regulations – Dr. Fabricant meets with the FDA, why ever would the NPA board or membership assume that he would be an effective representative to an agency division that was largely relieved upon his taking leave? And if someone else goes in his stead, what is the NPA paying for? But Jarrow Formulas is not an NPA member, and it is not our problem. It's NPA's. After all, the NDI Guidance will soon be re-issued and what is your "pit bull" going to say *this time*? "Never mind"? Accordingly, ask Dr. Fabricant to respond to Jarrow's 90-Request FOIA of March 4, 2014 – for the record, just as publicly as he trashed the supplement industry.

Sincerely,



Jarrow L. Rogovin

Enclosures: 15 attachments in a separate document.

cc: Sylvia M. Burwell, Secretary of HHS
Dr. Margaret Hamburg, FDA Commissioner
Michael Landa, FDA, CFSAN Director
Charlotte A. Christin, Acting Director, Division of Dietary Supplement Programs, CFSAN
Dr. Cara Welch, Regulatory Special Assistant
Dr. Daniel Fabricant, NPA
Dr. Corey Hilmas, NPA
Devon Powell (former COO and Dir of Member Services, NPA)
Dr. Pieter Cohen
Dr. Paul Offit
Diane Rehm on NPR radio
House Appropriations Committee (No attachments)
Government Oversight Committee (No attachments)
House Speaker John Boehner
House Committee on Energy and Commerce (No attachments)
Sen. Orin Hatch
Sen. Tom Harkin
Sen. John McCain
Sen. John Kyle
Sen. Tim Scott
Sen. Martin Heinrich
Cong. Darrel Issa
Cong. Michele Bachmann
Cong. Ed Royce
Cong. Eliot Engel
Cong. Bradley James "Brad" Sherman
Cong. Trent Franks
Cong. Paul Gosar
Cong. Peter Roskam
American Botanical Council
American Herbal Products Association
Council for Responsible Nutrition
UNPA
Citizens for Health
The Tan Sheet (Attn: Science Editor)
NutraIngredients U.S.A. (Attn: Science Editor)
Heather Wainer, Publisher, Whole Foods Magazine
Heather Wainer, Publisher, Whole Foods Magazine
Jon Benninger, VP, Virgo Publishing
Carlotta Mast, Managing Editor, newhope360.com
Nutrition Business Journal (Attn: Science Editor)
Nutritional Outlook website (Attn: Science Editor)
Washington Post (Attn: Science Editor)
Wall St. Journal (Attn: Science Editor)
New York Times (Attn: Science Editor)
Los Angeles Times (Attn: Science Editor)
San Francisco Chronicle (Attn: Science Editor)
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[1] In a previous article in the *Tan Sheet* (April 21, 2014), the FDA explained that this statistic meant that 70% of all GMP inspections (in 2013) found one or more compliance violations. (Malcolm Spicer, "Inspection Data Show 'Reality' of GMP Enforcement.") This means that even a small, technical violation of one sub-part in the GMP regulations was enough to place that dietary supplement company in the 70% "non-compliant" category. With this criterion, we would venture that up to 80% or more of food and drug companies would likewise be found "not in compliance."

[2] Accordingly, Jarrow Formulas is copying this correspondence to Drs. Cohen and Offit.

From:	Clapp, Nicole
To:	Welch, Cara; Pillsbury, Laura
Cc:	Durkin, Robert; Barrett, Kari; Natanblut, Sharon; Cruz, Marisa; Elkin, Ted
Subject:	Meeting with CRN, AHPA, NPA, UNPA and CHPA
Date:	Wednesday, August 26, 2015 10:10:24 AM

Hi Cara – No, I'm all set and sorry for the delay. I'll reach out to group from the last meeting to gauge availability the week of September 28th. I'll return to you with options.

I believe I may have touched on this previously however, once the date has been nailed down, will you loop in Exec Sec to coordinate the agenda/materials?

Thank you, Nicole

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Welch, Cara
Sent: Wednesday, August 26, 2015 10:07 AM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Durkin, Robert
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Nicole,
I wanted to touch base on this request – please let me know if you need anything from us.
Thanks
Cara

From: Welch, Cara
Sent: Thursday, August 20, 2015 12:41 PM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Thanks Nicole. Yes, we'd be expecting the same SMEs as the meeting yesterday with CRN.
Cara

From: Clapp, Nicole
Sent: Thursday, August 20, 2015 12:38 PM
To: Welch, Cara; Pillsbury, Laura
Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Hi Cara – Mike's in Milan for most of the week of the 21st. I'll look at the week of the 28th. I'll need to consider the availability of the SMEs as well... same folks as from the meeting with CRN

Nicole M. Clapp

Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Welch, Cara
Sent: Wednesday, August 19, 2015 3:45 PM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Nicole,
During our meeting with CRN today, Mike suggested we get a time scheduled for a meeting between OFVM/CFSAN and the 5 trade associations mentioned at the bottom of this email chain. CRN suggested we look at the week of Sept 21 or Sept 28 – could you provide some days/times for an hour long meeting with this group?
Thanks
Cara

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Pillsbury, Laura
Sent: Wednesday, July 22, 2015 7:15 PM
To: Welch, Cara; Durkin, Robert; Elkin, Ted
Cc: Cruz, Marisa; Clapp, Nicole
Subject: FW: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

As requested -

From: Clapp, Nicole
Sent: Thursday, July 16, 2015 4:00 PM
To: Steve Mister
Cc: Pillsbury, Laura; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Thanks, Steve – we'll review your request with Mike and get back to you as soon as possible.

Best, Nicole

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241

301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Steve Mister [mailto:SMister@crnusa.org]
Sent: Thursday, July 16, 2015 3:48 PM
To: Taylor, Michael R; Clapp, Nicole
Subject: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Mike – On behalf of my own organization, CRN, along with the American Herbal Products Association (AHPA), the Natural Products Association (NPA), the United Natural Products Alliance (UNPA) and the Consumer Healthcare Products Association (CHPA), I am contacting you to request a meeting. The five associations collectively represent all aspects of the dietary supplement industry. We would like to meet with you to discuss:

- Ongoing speculation that CFSAN may be considering elevating the Division of Dietary Supplement Programs to an Office level within the agency. The five industry organizations are supportive of this move and would like to learn more about this possibility and what we assistance might be able to provide (e.g., letters to members of Congress, letter of support to HHS, etc.) to make this a reality.
- The matter of a joint industry-FDA symposium examining dietary supplements. Mike, we have discussed this matter with you on a couple of occasions as well as numerous people throughout CFSAN over the past three years – Dr. Fabricant (when he was still at FDA), Dr. Welch, Mr. Spiller, Mr. Elkin. It was one of the topics you discussed with CRN in February of this year when we met with your office. For the past four years, the industry has been told repeatedly that there is no objection to this concept from FDA – in fact, the OTC industry has successfully conducted a similar program with CDER for the past ten years. We have sent multiple copies of a proposed agreement to FDA for your review and signature. Likewise, we have been told the agreement has received approval from FDA's ethics office and there is no internal objection to it. Yet we cannot get FDA to sign the agreement. We would like to discuss this matter and what can be done to move this initiative forward. (Most recently, the agreement was attached to my email to you dated June 17, 2015.)

Given vacation schedules, it may be difficult to schedule this meeting before mid-August, however, we will try to accommodate your own schedule and would invite you to provide us with a few dates that you might be available after August 10th. We anticipate the meeting would take about 30 minutes.

We will look forward to meeting with you and look forward to your response.

Steve Mister
President & CEO
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, D.C. 20036
(202) 204-7676
smister@crnusa.org
*Follow us on Twitter **@crn_supplements** and **@wannabewell**, **Facebook**, **Google+**, and **Vine***

From: NutraIngredients-USA
To: Welch, Cara
Subject: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source
Date: Thursday, January 12, 2017 11:23:12 AM

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12-Jan-2017

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NPA outlines top supplement-related legislative issues for PEOTUS Trump

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Sabinsa study supports DigeZyme's benefit in relieving post-exercise soreness

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- **AlaskOmega® leads the omega-3 concentrate market in Freshness** - AlaskOmega
- **Pycnogenol® Helps Curb Muscle Loss Due to Aging** - Horphag Research (USA) Inc.

From: NutraIngredients-USA
To: Welch, Cara
Subject: NPA launches warning letter database / It"s time to put whey and casein back together / GABA may enhance whey protein's muscle building potential / CoQ10 + NAD supplementation may aid chronic fatigue syndrome / Nitrosigine to come to EU market?
Date: Wednesday, July 27, 2016 10:50:53 AM

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From: NutraIngredients-USA
To: Welch_Cara
Subject: NPA petitions FDA to shelve supplement facts labeling rule / NSF supports Supplement OWL / Prebiotics promote satiety, but it"s hard to make the claim / New sports brand builds on branded ingredient foundation / Rise in high-dose vit D supplements use
Date: Tuesday, June 20, 2017 11:53:14 AM

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From: NutraIngredients-USA
To: Welch, Cara
Subject: NPA publishes book listing pre-DSHEA ingredients / Aker invests in promotion to boost omega-3 category / Gut diversity and health / Astaxanthin linked to 'skin rejuvenation' / Blackmores CEO interview
Date: Wednesday, November 08, 2017 12:38:14 PM

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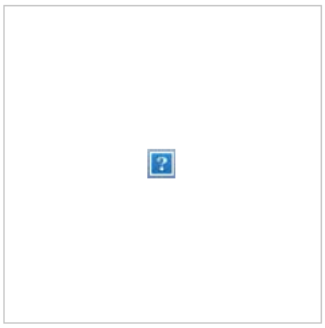

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From: NutraIngredients-USA
To: Welch_Cara
Subject: NPA sues board members for allegedly undermining it / How to work with AGs to reduce litigation risks / Licorice root benefit questioned / Advertising updates /
Date: Friday, February 05, 2016 11:47:49 AM

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EFSA provides update to ‘contradictory’ health claims advice

Contradictory advice on submitting probiotic health claims on immunity, pathogens and gastrointestinal functions, has led to scientific studies that fail to establish risk factors of a disease, a European Food Safety Authority (EFSA) panel member has said. .. Read

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The UK’s Advertising Standards Authority (ASA) says adverts for Omega Pharma’s weight management aid presents an “irresponsible approach to body image and confidence”... Read

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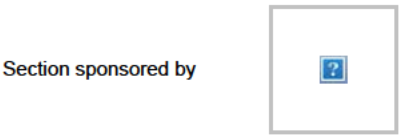

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From: NutraIngredients-USA
To: Welch, Cara
Subject: NPA to develop 'safe harbor' list for dietary ingredients / Warning letter provides lesson for citing science / What's going on with the NY AG 7? / Consumers & botanicals? / NAI"s record results / Conventional foods & structure/function claims / BC30 news
Date: Wednesday, September 21, 2016 1:02:16 PM

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29-Sep-2016

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Le Belem - 355, rue Vendemiaire - 34000 Montpellier - France
https://www.william-reed.com

From: Durkin, Robert
To: Welch, Cara; Robinson, Latasha A
Subject: Re: AHPA NPA Joint Letter
Date: Monday, August 31, 2015 4:32:25 PM

I'm in.....a call in number would be great.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Welch, Cara
Sent: Monday, August 31, 2015 4:26 PM
To: Durkin, Robert; Robinson, Latasha A
Subject: RE: AHPA NPA Joint Letter

Do both of you want to be on this call? Shall I set up a call-in number?

From: Nickerson, Louisa
Sent: Monday, August 31, 2015 4:25 PM
To: Welch, Cara
Cc: Durkin, Robert; Robinson, Latasha A
Subject: Re: AHPA NPA Joint Letter

Let's make it 4:15. Please call me at (b) (6) .

From: Welch, Cara
Sent: Monday, August 31, 2015 3:49 PM
To: Nickerson, Louisa
Cc: Durkin, Robert; Robinson, Latasha A
Subject: RE: AHPA NPA Joint Letter

Tomorrow works better for Bob and I – could we talk at 2:30 (we'll be en route to WO but can get on a call)? Or maybe 4:15?

From: Nickerson, Louisa
Sent: Monday, August 31, 2015 1:59 PM
To: Welch, Cara
Cc: Durkin, Robert; Robinson, Latasha A
Subject: Re: AHPA NPA Joint Letter

Sure. I have an appointment now but should be free by 5 if that's not too late. Otherwise I could talk tomorrow after 2.

From: Welch, Cara
Sent: Monday, August 31, 2015 1:46 PM
To: Nickerson, Louisa
Cc: Durkin, Robert; Robinson, Latasha A
Subject: FW: AHPA NPA Joint Letter

Louisa,
I know you're not supposed to be working but Bob said (b) (5)

(b) (5) – could I set up a time to speak with you on this topic so we can make sure we're giving a consistent response?
Thanks
Cara

From: Corey Hilmas [mailto:corey.hilmas@npainfo.org]
Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
Subject: AHPA NPA Joint Letter

Dear Dr. Welch and Ms. Robinson,

The American Herbal Products Association (AHPA) and the Natural Products Association (NPA) have drafted a joint letter requesting clarification on the labeling of an herbal dietary ingredient for use in dietary supplements, pursuant to 21 CFR 101.4(h). We hope that you would be able to shed light and provide direction on this issue for us.

Sincerely,

Corey J. Hilmas, M.D., Ph.D.
Senior Vice President of Scientific & Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office 202.223.0101 x109
Direct 202.204.4725
Cell 443.632.8365
Fax 202.223.0250
www.NPAinfo.org

From: Durkin, Robert
To: Welch, Cara; Nickerson, Louisa
Cc: Robinson, Latasha A
Subject: RE: AHPA NPA Joint Letter
Date: Monday, August 31, 2015 1:53:07 PM
Attachments: RE Attorney Work Product (Confidential) - For Investigative Purposes.msg

---

I'm not sure if the conversation was (b) (5) ; but was on the general topic of naming conventions under 21 CFR 101.4

Seems the issues may be related.

From: Welch, Cara
Sent: Monday, August 31, 2015 1:47 PM
To: Nickerson, Louisa
Cc: Durkin, Robert; Robinson, Latasha A
Subject: FW: AHPA NPA Joint Letter

Louisa,
I know you're not supposed to be working but Bob said (b) (5) – could I set up a time to speak with you on this topic so we can make sure we're giving a consistent response?
Thanks
Cara

From: Corey Hilmas [mailto:corey.hilmas@npainfo.org]
Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
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Corey J. Hilmas, M.D., Ph.D.
Senior Vice President of Scientific & Regulatory Affairs
Natural Products Association
1773 T Street, NW

From: Durkin, Robert
To: Welch, Cara
Subject: RE: AHPA NPA Joint Letter
Date: Monday, August 31, 2015 1:43:54 PM

Thanks. Did you ever get a down-load of Louisa's conversation on the issue?

From: Welch, Cara
Sent: Monday, August 31, 2015 1:40 PM
To: Durkin, Robert
Subject: FW: AHPA NPA Joint Letter

From: Corey Hilmas [mailto:corey.hilmas@npainfo.org]
Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
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Washington, DC 20009
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Direct 202.204.4725
Cell 443.632.8365
Fax 202.223.0250
www.NPAinfo.org

From: Nickerson, Louisa
To: Welch, Cara
Subject: Re: AHPA NPA Joint Letter
Date: Monday, August 31, 2015 4:36:53 PM

Sure. A meeting invitation would be good; that way I'll get a reminder.

From: Welch, Cara
Sent: Monday, August 31, 2015 4:34 PM
To: Nickerson, Louisa
Cc: Durkin, Robert; Robinson, Latasha A
Subject: RE: AHPA NPA Joint Letter

Louisa,
I think we'll be in 4 different places at this time so can you dial into the conf line below? I'll also send around a meeting invite for our calendars (I'm not sure how much you're on your computer while "on leave")
Thanks
Cara

Dial: (b) (6)
Conf ID: (b) (6)

From: Nickerson, Louisa
Sent: Monday, August 31, 2015 4:25 PM
To: Welch, Cara
Cc: Durkin, Robert; Robinson, Latasha A
Subject: Re: AHPA NPA Joint Letter

Let's make it 4:15. Please call me at (b) (6)

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Cc: Durkin, Robert; Robinson, Latasha A
Subject: RE: AHPA NPA Joint Letter

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To: Welch, Cara
Cc: Durkin, Robert; Robinson, Latasha A
Subject: Re: AHPA NPA Joint Letter

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Cc: Durkin, Robert; Robinson, Latasha A
Subject: FW: AHPA NPA Joint Letter

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Thanks
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Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
Subject: AHPA NPA Joint Letter

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Direct 202.204.4725
Cell 443.632.8365
Fax 202.223.0250
www.NPAinfo.org

From:	Benjamin, Dianne
To:	Clapp, Nicole; McDonald, Laura *
Cc:	Durkin, Robert; Welch, Cara; Novak, Benjamin
Subject:	RE: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm
Date:	Friday, September 25, 2015 10:38:56 AM

Nicole –

It would be helpful to have that information….set up at Wiley and WO is a bit different.

Thanks.

Dianne

From: Clapp, Nicole
Sent: Friday, September 25, 2015 10:13 AM
To: Benjamin, Dianne; McDonald, Laura *
Cc: Durkin, Robert; Welch, Cara; Novak, Benjamin; Clapp, Nicole
Subject: RE: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm

Looks good to me, Dianne – I'll send out the updated invite with attachments and dial in now. I'll input this into Lobby guard for entry into WO on Monday. I won't need specific car information but I will send you the email to send to those that are driving regarding parking etc. assuming you haven't provided it to them already

thanks

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Benjamin, Dianne
Sent: Thursday, September 24, 2015 3:01 PM
To: Clapp, Nicole; McDonald, Laura *
Cc: Durkin, Robert; Welch, Cara; Novak, Benjamin
Subject: FW: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm

Hi Nicole,

This is what we have so far in terms of materials for this meeting on Monday with Mike and the trade associations representing the dietary supplement industry.

I am told that Dan Fabricant and Corey Hilmas will participate by phone. –Can you provide a call-in? Lastly, if there are others you know of that will be attending for OFVM, I' d be happy to update the attached.

Of the attendees listed below only two of them indicated that they will be driving:
Michael Kelly will need to park a (b) (6), and Steve Mister – (b) (6). (We advised them that parking is limited at White Oak.)

Michael McGuffin, President, American Herbal Products Association (AHPA)
Tony Young (Kleinfeld Kaplan & Becker), General Counsel, AHPA
Scott Melville President & CEO, Consumer Healthcare Products Association (CHPA)
Jay Sirois, Director, Regulatory and Scientific Affairs, CHPA
Steve Mister, President & CEO, Council for Responsible Nutrition (CRN)
Douglas "Duffy" MacKay, Sr. Vice President Scientific and Regulatory Affairs, CRN
Daniel Fabricant, Ph.D, CEO & Executive Director, Natural Products Association (NPA)
Michael Kelley, Director, Government Affairs, NPA
Corey J. Hilmas, M.D., Ph.D, Senior Vice President of Scientific and Regulatory Affairs, NPA (by phone)
Patricia Knight, consultant to United Natural Products Alliance

Thanks.
Dianne

From: Welch, Cara
Sent: Thursday, September 10, 2015 4:21 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert; Benjamin, Dianne; Clapp, Nicole
Subject: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm

All,
We've scheduled a meeting to discuss dietary supplement issues with your 5 trade associations on Monday, Sept 28, at 12:30pm. We have an hour scheduled for the meeting and it will be at the White Oak campus. I apologize for the slight time change from what I proposed before – Mike's schedule was adjusted in the last couple weeks.

When your initial request for a meeting came in a couple months ago, you'd requested a meeting to discuss elevating DDSP from a division to an office and the matter of a joint industry-FDA symposium examining dietary supplements. I'm not sure if these are still your agenda items but I think we'd like a meeting to discuss how to elevate and redefine dietary supplement regulation and opportunities for FDA collaboration. Please let me know if you have additional items you'd like included.

Finally, I've copied Ms. Dianne Benjamin from OFVM's Executive Secretariat Staff – she'll coordinate agenda, materials, and other preparation as needed.
Thank you all
Cara

From: Welch, Cara
Sent: Friday, September 04, 2015 3:20 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

All, I just wanted to touch base on this request – I've heard from some of the associations but hope to get a meeting scheduled on Mike and Ted's calendars right away next week. Please let me know if the two times offered below are acceptable.
Thank you and I hope everyone has a good holiday weekend.
Cara

From: Welch, Cara
Sent: Monday, August 31, 2015 2:12 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Michael, Scott, Steve, Dan, and Loren,

I hope you're all well. DDSP wanted to reach out re: scheduling a meeting with Mike Taylor, Ted Elkin, DDSP, and others at OFVM on the topics mentioned below. Due to the busy schedules of Mike and Ted, as well as the desire to get this meeting scheduled soon, I can only offer Monday, 9/28, at 1-2pm or 4:30-5:30pm. Please let me know as soon as possible if one of these dates can be accommodated – we will certainly have a call-in option if folks can't attend in person.

Thanks
Cara

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 240-402-2333
Fax: 301-436-2636

From: Steve Mister [mailto:SMister@crnusa.org]
Sent: Thursday, July 16, 2015 3:48 PM
To: Taylor, Michael R; Clapp, Nicole
Subject: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Mike – On behalf of my own organization, CRN, along with the American Herbal Products Association (AHPA), the Natural Products Association (NPA), the United Natural Products Alliance (UNPA) and the Consumer Healthcare Products Association (CHPA), I am contacting you to request a meeting.

The five associations collectively represent all aspects of the dietary supplement industry. We would like to meet with you to discuss:

- Ongoing speculation that CFSAN may be considering elevating the Division of Dietary Supplement Programs to an Office level within the agency. The five industry organizations are supportive of this move and would like to learn more about this possibility and what we assistance might be able to provide (e.g., letters to members of Congress, letter of support to HHS, etc.) to make this a reality.
- The matter of a joint industry-FDA symposium examining dietary supplements. Mike, we have discussed this matter with you on a couple of occasions as well as numerous people throughout CFSAN over the past three years – Dr. Fabricant (when he was still at FDA), Dr. Welch, Mr. Spiller, Mr. Elkin. It was one of the topics you discussed with CRN in February of this year when we met with your office. For the past four years, the industry has been told repeatedly that there is no objection to this concept from FDA – in fact, the OTC industry has successfully conducted a similar program with CDER for the past ten years. We have sent multiple copies of a proposed agreement to FDA for your review and signature. Likewise, we have been told the agreement has received approval from FDA's ethics office and there is no internal objection to it. Yet we cannot get FDA to sign the agreement. We would like to discuss this matter and what can be done to move this initiative forward. (Most recently, the agreement was attached to my email to you dated June 17, 2015.)

Given vacation schedules, it may be difficult to schedule this meeting before mid-August, however, we will try to accommodate your own schedule and would invite you to provide us with a few dates that you might be available after August 10th. We anticipate the meeting would take about 30 minutes.

We will look forward to meeting with you and look forward to your response.

Steve Mister
President & CEO
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, D.C. 20036
(202) 204-7676
smister@crnusa.org

From:	Daniel Fabricant, Ph.D.
To:	Benjamin, Dianne
Cc:	Welch, Cara
Subject:	Re: CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting: 9/28 12:30pm --Security Forms, Map and LobbyGuard -- please distribute
Date:	Monday, September 28, 2015 8:25:34 AM

Thanks Dianne. What is the best number to dial in?

Sent from my iPhone

On Sep 28, 2015, at 3:30 AM, Benjamin, Dianne <Dianne.Benjamin@fda.hhs.gov> wrote:

> Good morning - you are confirmed to meet with Mike Taylor on Monday, 9/28 at 12:30pm.
>
> The meeting will be held at our White Oak offices - 10903 New Hampshire Avenue, Silver Spring, MD 20993. Please note, you'll be entering the campus via the main entrance/Building 1 off Mahan Road. Please bring your U. S. Government issued ID with you for check in.
>
> If arriving by private car, I've attached a map of the campus which also indicates where visitor parking is located. There's a shuttle bus available that can bring you to Building 1. Please arrive at least 15 minutes early to allow for travel to the main entrance, security and escort to the conference room.
>
> I've also attached a form that when presented to security, will make for easier entry into our building. There's no issue if you aren't able to print it out. Also, all participants are accounted for on the attached form.
>
> When you arrive, please ask the guard to call Nicole Clapp as she'll escort you to Mike's office. Her number is 301-796-4500 I if needed. Please let me know if you have any questions.
>
> Best Regards,
>
> ---
>
> **From:** Welch, Cara
> **Sent:** Thursday, September 10, 2015 4:21 PM
> **To:** mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
> **Cc:** Durkin, Robert; Benjamin, Dianne; Clapp, Nicole
> **Subject:** CRN, AHPA, NPA, UNPA and CHPA/FDA Meeting Scheduled: 9/28 12:30pm
>
> All,
> We've scheduled a meeting to discuss dietary supplement issues with your 5 trade

associations on Monday, Sept 28, at 12:30pm. We have an hour scheduled for the meeting and it will be at the White Oak campus. I apologize for the slight time change from what I proposed before – Mike's schedule was adjusted in the last couple weeks.

When your initial request for a meeting came in a couple months ago, you'd requested a meeting to discuss elevating DDSP from a division to an office and the matter of a joint industry-FDA symposium examining dietary supplements. I'm not sure if these are still your agenda items but I think we'd like a meeting to discuss how to elevate and redefine dietary supplement regulation and opportunities for FDA collaboration. Please let me know if you have additional items you'd like included.

Finally, I've copied Ms. Dianne Benjamin from OFVM's Executive Secretariat Staff – she'll coordinate agenda, materials, and other preparation as needed.
Thank you all
Cara

From: Welch, Cara
Sent: Friday, September 04, 2015 3:20 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

All, I just wanted to touch base on this request – I've heard from some of the associations but hope to get a meeting scheduled on Mike and Ted's calendars right away next week. Please let me know if the two times offered below are acceptable. Thank you and I hope everyone has a good holiday weekend.
Cara

From: Welch, Cara
Sent: Monday, August 31, 2015 2:12 PM
To: mmcguffin@ahpa.org; melville@chpa.org; Steve Mister (SMister@crnusa.org); Daniel Fabricant, Ph.D. (Daniel.Fabricant@NPAinfo.org); loren@unpa.com
Cc: Durkin, Robert (Robert.Durkin@fda.hhs.gov); OC-OFVM-ExecSec; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Michael, Scott, Steve, Dan, and Loren,

I hope you're all well. DDSP wanted to reach out re: scheduling a meeting with Mike Taylor, Ted Elkin, DDSP, and others at OFVM on the topics mentioned below. Due to the busy schedules of Mike and Ted, as well as the desire to get this meeting scheduled soon, I can only offer Monday, 9/28, at 1-2pm or 4:30-5:30pm. Please let me know as soon as possible if one of these dates can be accommodated – we will certainly have a call-in option if folks can't attend in person.

Thanks

Cara

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 240-402-2333
Fax: 301-436-2636

From: Steve Mister [mailto:SMister@crnusa.org]
Sent: Thursday, July 16, 2015 3:48 PM
To: Taylor, Michael R; Clapp, Nicole
Subject: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Mike – On behalf of my own organization, CRN, along with the American Herbal Products Association (AHPA), the Natural Products Association (NPA), the United Natural Products Alliance (UNPA) and the Consumer Healthcare Products Association (CHPA), I am contacting you to request a meeting. The five associations collectively represent all aspects of the dietary supplement industry. We would like to meet with you to discuss:

- Ongoing speculation that CFSAN may be considering elevating the Division of Dietary Supplement Programs to an Office level within the agency. The five industry organizations are supportive of this move and would like to learn more about this possibility and what we assistance might be able to provide (e.g., letters to members of Congress, letter of support to HHS, etc.) to make this a reality.
- The matter of a joint industry-FDA symposium examining dietary supplements. Mike, we have discussed this matter with you on a couple of occasions as well as numerous people throughout CFSAN over the past three years – Dr. Fabricant (when he was still at FDA), Dr. Welch, Mr. Spiller, Mr. Elkin. It was one of the topics you discussed with CRN in February of this year when we met with your office. For the past four years, the industry has been told repeatedly that there is no objection to this concept from FDA – in fact, the OTC industry has successfully conducted a similar program with CDER for the past ten years. We have sent multiple copies of a proposed agreement to FDA for your review and signature. Likewise, we have been told the agreement has received approval from FDA's ethics office and there is no internal objection to it. Yet we cannot get FDA to sign the agreement. We would like to discuss this matter and what can be done to move this initiative forward. (Most recently, the agreement was attached to my email to you dated June 17, 2015.)

Given vacation schedules, it may be difficult to schedule this meeting before mid-August, however, we will try to accommodate your own schedule and would invite you to provide us with a few dates that you might be available after August 10th. We anticipate the meeting would take about 30 minutes.
We will look forward to meeting with you and look forward to your response.

Steve Mister
President & CEO
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, D.C. 20036
(202) 204-7676
smister@crnusa.org
Follow us on Twitter @crn_supplements and @wannabewell, Facebook, Google+, and Vine

<mime-attachment>

<Parking.pdf>

From:	DeLancey, Siobhan
To:	Poos, Mary
Cc:	Spiller, Philip C; Yanish, Nancy; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.; Mozersky, Robert; Shapinsky, David; Schor, Danielle
Subject:	RE: For ONLDS signoff: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Date:	Wednesday, November 05, 2014 2:36:31 PM

Perfect! Thanks, Mary! Nancy, I will clean this up and send to you for OCD clearance in a minute.

Siobhan DeLancey, RVT, MPH
O |240-402-9973
M|202-510-4177

From: Poos, Mary
Sent: Wednesday, November 05, 2014 2:34 PM
To: DeLancey, Siobhan
Cc: Spiller, Philip C; Yanish, Nancy; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.; Mozersky, Robert; Shapinsky, David; Schor, Danielle
Subject: FW: For ONLDS signoff: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Importance: High

Hi Siobhan,

Attached is the ONLDS cleared version of the response. Please note (b) (5) [redacted]. You may want to tinker with how I presented it, which would be fine with me.

Mary

Mary I. Poos, Ph.D.
Deputy Director
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
240-402-1761

From: DeLancey, Siobhan
Sent: Wednesday, November 05, 2014 12:29 PM
To: Poos, Mary; Spiller, Philip C; Yanish, Nancy
Cc: Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.; Mozersky, Robert; Shapinsky, David; Schor, Danielle
Subject: For ONLDS signoff: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Importance: High

Phil and Mary, this proposed response to the NPA letter is now ready for ONLDS' review and approval—it has been reviewed and edited or cleared by everyone on the CC line. Nancy, I am including you so that you are aware it will come to you next for OCD clearance.

I am getting pushed by OEA, so request ONLDS clearance by COB today. Please advise if that is not possible.

Thanks!

From: DeLancey, Siobhan
Sent: Wednesday, November 05, 2014 6:28 AM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Just putting this front of mind for follow-up this morning. I received comments from Charlotte last night and they are incorporated in the attachment.

One thing that we discussed last night was the language regarding (b) (5). Whether or not this particular point winds up in the response to NPA, I do expect the Tan Sheet reporter will ask about, so it would be better to noodle it out ahead of time.

I'll be at CFSAN today and can stop by for in-person discussion if needed. Thanks!

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Sent: Tuesday, November 04, 2014 4:02 PM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Hi all,

I've been tasked with drafting a response to the letter writer. NPA has also shared the letter with the Tan Sheet, which is requesting a response as well. I have informed the reporter that we plan to respond directly to NPA first. Please take a look at what I've drafted below and see if it accurately characterizes our position. I've also attached the original letter, and you can reference the CU itself at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm420349.htm.

Once you have provided your comments, I will send a revised version for CFSAN OCD clearance and then to OEA.

(b) (5)

From: Poos, Mary
Sent: Monday, November 03, 2014 1:52 PM
To: Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC
Cc: Shapinsky, David; Welch, Cara; Levy, Dan D.; Schor, Danielle
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

We did not develop it, CDER did, but I and others reviewed and cleared it. I think NPA's letter is (b) (5) . There is (b) (5) with respect to what it says.

From: Spiller, Philip C
Sent: Monday, November 03, 2014 1:08 PM
To: Mozersky, Robert; Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle
Cc: Shapinsky, David; Poos, Mary; Welch, Cara
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Idle curiosity question for today: Did DDSP participate in developing this consumer update?

From: Mozersky, Robert
Sent: Monday, November 03, 2014 12:52 PM
To: Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle

Cc: Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

The article does not mention that dietary supplements should have labels.
Its point is that consumer's should know what they are taking by asking a health care provider.

Robert Mozersky, D.O.
Medical Officer
Division of Dietary Supplement Products
HFS-810
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Phone: 240-402-1445
FAX #: 301-436-2636

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 12:33 PM
To: Levy, Dan D.; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks. Will circle back later.

From: Levy, Dan D.
Sent: Monday, November 03, 2014 12:32 PM
To: Christin, Charlotte - OC; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

This looks more like a (b) (5) .

I think the only response, if any, (b) (5) .

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 11:53 AM
To: Schor, Danielle
Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks, Dani. I'm tied up in meetings until later this afternoon and will look at this then.

From: Schor, Danielle
Sent: Monday, November 03, 2014 11:49 AM
To: Christin, Charlotte - OC
Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: FW: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Charlotte

I know you are no longer involved with dietary supplements, but this consumer update was prepared some time ago and I wanted to include you as well as Dan and Robert, since he is quoted.

We received this comment below from the Natural Products Assoc. on the consumer update, which is linked in NPA's email. We don't necessarily think there is anything wrong with the Consumer Update and NPA may be providing an opinion that we don't share. I just wanted to get everyone's take on how we should respond.

Many thanks.

Dani Schor, R.D.¦ Communications and Public Engagement Staff
FDA Office of Foods and Veterinary Medicine
301.796.5404 (phone) ¦240.205.2886 (cell)
danielle.schor@fda.hhs.gov ¦ WO Bldg 1, room 3240

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Friday, October 31, 2014 03:53 PM
To: Immergut, Steven
Cc: Taylor, Michael R; Natanblut, Sharon
Subject: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Dear Mr. Immergut,

As the leading trade association representing the dietary supplement industry, the Natural Products Association (NPA) is requesting a few clarifications be made to the Food and Drug Administration's (FDA) recent consumer update, Mixing Medications and Dietary Supplements Can Endanger Your Health. We are disappointed to see this type of communication from the agency, as it seems sensational in nature, and provides misleading information related to dietary supplements as compared to other foods.

As you more than likely are aware, the FDA has never pursued the requirement of a label warning for dietary supplements regarding their interaction with pharmaceuticals. The FDA has never found it to be material fact to change consumer behavior consistent with the Central Hudson test[1] for labeling. Your consumer update suggests that some dietary supplements need a warning statement, when compelling such a warning label on dietary supplement products would require convincing evidence rather than mere speculation or furthering a stated interest by informing consumers. The

Supreme Court's use of the Central Hudson test should be the standard by which food law regulations are analyzed, whether bans, required disclosures or warnings. In applying the Central Hudson test, the Second Circuit Court concluded that the regulating agency did not claim that health or safety concerns prompted the passage of a certain labeling law, but instead found its interest relied on informing the consumer. Therefore, the agency interest "in the public right to know" was "insufficient to justify compromising protected constitutional rights" under the First Amendment.[2]

It is the agency's burden to demonstrate the harms it recites are real and that its restriction will, in fact, alleviate them to a material degree. Therefore, absent material fact with evidence or empirical data, NPA believes it is misleading for the agency to draw the conclusion in a statement to consumers that dietary supplements are putting them at risk more than other categories of food. NPA has supported the FDA's mission on protecting the public health, including adequate funding for the agency, and adding statutory authority (i.e., serious adverse event reporting requirement); however, it is unclear as to why the FDA positioned its communication that dietary supplements pose more risk or harm than other foods when used with pharmaceuticals. If the FDA seeks to make such a statement, it must have compelling evidence. The comments in the consumer advisory were irresponsible in the absence of material fact to compel a label warning on dietary supplements.

Furthermore, there already exists required warning statements on medications to warn consumers regarding potentially dangerous combinations with that particular drug product. The consumer update reads, "Some consumers may believe that a so-called 'natural' product, such as an herbal supplement or fish oil, can't hurt them. ... For example, many weight loss products claim to be 'all-natural' or 'herbal,' but their ingredients may interact with medications or may be dangerous for people with certain medical conditions." This indicates that the supplement is posing a risk, when, in fact, the particular drug product is already required to be properly labeled with appropriate warning statements regarding side effects. The messaging here creates confusion, as now consumers may falsely believe that the supplements they are taking each day should contain warning statements or that the products are misbranded because they fail to declare a particular warning statement. We recommend editing your consumer piece to reflect this point. Moreover, if the agency is concerned with a specific dietary ingredient found in supplement form, why isn't it making similar warnings on the whole food version? For example, the consumer update specifically references fish oil, but yet the agency hasn't made the same statement regarding fatty fish, such as salmon, that are high in omega-3 fatty acids.

Finally, NPA takes issue with the section, "What is FDA's Role." The dietary supplement industry has many robust agency regulations in place. Dietary supplements are regulated as a food product under the Dietary Supplement Health and Education Act, and consistently meet the government and industry standards that have been set. In fact, dietary supplements are the only category of food where submission of serious adverse event reports are a mandatory requirement. The same reporting requirement is not required of other foods, such as grapefruits, that are known to interact with various medications. Additionally, dietary supplement labels must carry contact information for consumers to report serious adverse events. No other categories of food are required to do this. The agency must ensure it is even-handed and science-based toward public health concerns to keep consumers safe.

NPA supports the position that consumers should consult their physician any time they are supplementing their diet, making a change in their diet, or seeking advice on a medication. A more important focus for this consumer update would have been to emphasize the importance of talking with a doctor before starting any medication or dietary supplement or making any changes to one's health care regimen.

NPA asks that you please clarify the inaccuracies in this piece so that consumers can be better educated on the topic at hand.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org


[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).
[1] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

[1]

From:	Levy, Dan D.
To:	Welch, Cara; DeLancey, Siobhan
Subject:	RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Date:	Wednesday, November 05, 2014 10:15:04 AM

Thanks Cara

I have no additional edits.
Dan

From: Welch, Cara
Sent: Wednesday, November 05, 2014 8:43 AM
To: DeLancey, Siobhan; Levy, Dan D.
Subject: RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Attached are a few edits from me
Cara

From: DeLancey, Siobhan
Sent: Wednesday, November 05, 2014 6:28 AM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

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One thing that we discussed last night was the language regarding (b) (5) Whether or not this particular point winds up in the response to NPA, I do expect the Tan Sheet reporter will ask about, so it would be better to noodle it out ahead of time.

I'll be at CFSAN today and can stop by for in-person discussion if needed. Thanks!

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Hi all,

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Thanks. Will circle back later.

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Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

This looks more like a litigation brief than a friendly note from their communications director.

I think the only response, if any, is that we review each labeling situation on a case by case basis and we always value input from NPA and other stakeholders on how to do that.

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 11:53 AM
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Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
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Dani Schor, R.D.¦ Communications and Public Engagement Staff
FDA Office of Foods and Veterinary Medicine
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danielle.schor@fda.hhs.gov ¦ WO Bldg 1, room 3240

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To: Immergut, Steven
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omega-3 fatty acids.

Finally, NPA takes issue with the section, "What is FDA's Role." The dietary supplement industry has many robust agency regulations in place. Dietary supplements are regulated as a food product under the Dietary Supplement Health and Education Act, and consistently meet the government and industry standards that have been set. In fact, dietary supplements are the only category of food where submission of serious adverse event reports are a mandatory requirement. The same reporting requirement is not required of other foods, such as grapefruits, that are known to interact with various medications. Additionally, dietary supplement labels must carry contact information for consumers to report serious adverse events. No other categories of food are required to do this. The agency must ensure it is even-handed and science-based toward public health concerns to keep consumers safe.

NPA supports the position that consumers should consult their physician any time they are supplementing their diet, making a change in their diet, or seeking advice on a medication. A more important focus for this consumer update would have been to emphasize the importance of talking with a doctor before starting any medication or dietary supplement or making any changes to one's health care regimen.

NPA asks that you please clarify the inaccuracies in this piece so that consumers can be better educated on the topic at hand.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org

[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).
[1] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

From:	DeLancey, Siobhan
To:	Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc:	Shapinsky, David; Schor, Danielle
Subject:	RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Date:	Wednesday, November 05, 2014 6:27:47 AM
Attachments:	DS interaction NPA letter.doc DS interaction response v2.doc

Just putting this front of mind for follow-up this morning. I received comments from Charlotte last night and they are incorporated in the attachment.

One thing that we discussed last night was the language regarding (b) (5) Whether or not this particular point winds up in the response to NPA, I do expect the Tan Sheet reporter will ask about, so it would be better to noodle it out ahead of time.

I'll be at CFSAN today and can stop by for in-person discussion if needed. Thanks!

From: DeLancey, Siobhan
Sent: Tuesday, November 04, 2014 4:02 PM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Hi all,

I've been tasked with drafting a response to the letter writer. NPA has also shared the letter with the Tan Sheet, which is requesting a response as well. I have informed the reporter that we plan to respond directly to NPA first. Please take a look at what I've drafted below and see if it accurately characterizes our position. I've also attached the original letter, and you can reference the CU itself at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm420349.htm.

Once you have provided your comments, I will send a revised version for CFSAN OCD clearance and then to OEA.

(b) (5)

(b) (5)

From: Poos, Mary
Sent: Monday, November 03, 2014 1:52 PM
To: Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC
Cc: Shapinsky, David; Welch, Cara; Levy, Dan D.; Schor, Danielle
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

We did not develop it, CDER did, but I and others reviewed and cleared it. I think NPA's letter is (b) (5) . There is nothing for us to do (b) (5) with respect to what it says.

From: Spiller, Philip C
Sent: Monday, November 03, 2014 1:08 PM
To: Mozersky, Robert; Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle
Cc: Shapinsky, David; Poos, Mary; Welch, Cara
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Idle curiosity question for today: Did DDSP participate in developing this consumer update?

From: Mozersky, Robert
Sent: Monday, November 03, 2014 12:52 PM
To: Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle
Cc: Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

The article does not mention that dietary supplements should have labels.
Its point is that consumer's should know what they are taking by asking a health care provider.

Robert Mozersky, D.O.
Medical Officer
Division of Dietary Supplement Products
HFS-810
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Phone: 240-402-1445
FAX #: 301-436-2636

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 12:33 PM
To: Levy, Dan D.; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks. Will circle back later.

From: Levy, Dan D.
Sent: Monday, November 03, 2014 12:32 PM
To: Christin, Charlotte - OC; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

This looks more like a litigation brief than a friendly note from their communications director.

I think the only response, if any, is that we review each labeling situation on a case by case basis and we always value input from NPA and other stakeholders on how to do that.

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 11:53 AM
To: Schor, Danielle
Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks, Dani. I'm tied up in meetings until later this afternoon and will look at this then.

From: Schor, Danielle
Sent: Monday, November 03, 2014 11:49 AM
To: Christin, Charlotte - OC

Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: FW: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Charlotte

I know you are no longer involved with dietary supplements, but this consumer update was prepared some time ago and I wanted to include you as well as Dan and Robert, since he is quoted.

We received this comment below from the Natural Products Assoc. on the consumer update, which is linked in NPA's email. We don't necessarily think there is anything wrong with the Consumer Update and NPA may be providing an opinion that we don't share. I just wanted to get everyone's take on how we should respond.

Many thanks.

Dani Schor, R.D.¦ Communications and Public Engagement Staff
FDA Office of Foods and Veterinary Medicine
301.796.5404 (phone) ¦240.205.2886 (cell)
danielle.schor@fda.hhs.gov ¦ WO Bldg 1, room 3240

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Friday, October 31, 2014 03:53 PM
To: Immergut, Steven
Cc: Taylor, Michael R; Natanblut, Sharon
Subject: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Dear Mr. Immergut,

As the leading trade association representing the dietary supplement industry, the Natural Products Association (NPA) is requesting a few clarifications be made to the Food and Drug Administration's (FDA) recent consumer update, Mixing Medications and Dietary Supplements Can Endanger Your Health. We are disappointed to see this type of communication from the agency, as it seems sensational in nature, and provides misleading information related to dietary supplements as compared to other foods.

As you more than likely are aware, the FDA has never pursued the requirement of a label warning for dietary supplements regarding their interaction with pharmaceuticals. The FDA has never found it to be material fact to change consumer behavior consistent with the Central Hudson test[1] for labeling. Your consumer update suggests that some dietary supplements need a warning statement, when compelling such a warning label on dietary supplement products would require convincing evidence rather than mere speculation or furthering a stated interest by informing consumers. The Supreme Court's use of the Central Hudson test should be the standard by which food law regulations are analyzed, whether bans, required disclosures or warnings. In applying the Central Hudson test, the Second Circuit Court concluded that the regulating agency did not claim that health or safety concerns prompted the passage of a certain labeling law, but instead found its interest relied on informing the consumer. Therefore, the agency interest "in the public right to know" was "insufficient to justify compromising protected constitutional rights" under the First Amendment.[2]

It is the agency's burden to demonstrate the harms it recites are real and that its restriction will, in fact, alleviate them to a material degree. Therefore, absent material fact with evidence or empirical data, NPA believes it is misleading for the agency to draw the conclusion in a statement to consumers that dietary supplements are putting them at risk more than other categories of food. NPA has supported the FDA's mission on protecting the public health, including adequate funding for the agency, and adding statutory authority (i.e., serious adverse event reporting requirement); however, it is unclear as to why the FDA positioned its communication that dietary supplements pose more risk or harm than other foods when used with pharmaceuticals. If the FDA seeks to make such a statement, it must have compelling evidence. The comments in the consumer advisory were irresponsible in the absence of material fact to compel a label warning on dietary supplements.

Furthermore, there already exists required warning statements on medications to warn consumers regarding potentially dangerous combinations with that particular drug product. The consumer update reads, "Some consumers may believe that a so-called 'natural' product, such as an herbal supplement or fish oil, can't hurt them. ... For example, many weight loss products claim to be 'all-natural' or 'herbal,' but their ingredients may interact with medications or may be dangerous for people with certain medical conditions." This indicates that the supplement is posing a risk, when, in fact, the particular drug product is already required to be properly labeled with appropriate warning statements regarding side effects. The messaging here creates confusion, as now consumers may falsely believe that the supplements they are taking each day should contain warning statements or that the products are misbranded because they fail to declare a particular warning statement. We recommend editing your consumer piece to reflect this point. Moreover, if the agency is concerned with a specific dietary ingredient found in supplement form, why isn't it making similar warnings on the whole food version? For example, the consumer update specifically references fish oil, but yet the agency hasn't made the same statement regarding fatty fish, such as salmon, that are high in omega-3 fatty acids.

Finally, NPA takes issue with the section, "What is FDA's Role." The dietary supplement industry has many robust agency regulations in place. Dietary supplements are regulated as a food product under the Dietary Supplement Health and Education Act, and consistently meet the government and industry standards that have been set. In fact, dietary supplements are the only category of food where submission of serious adverse event reports are a mandatory requirement. The same reporting requirement is not required of other foods, such as grapefruits, that are known to interact with various medications. Additionally, dietary supplement labels must carry contact information for consumers to report serious adverse events. No other categories of food are required to do this. The agency must ensure it is even-handed and science-based toward public health concerns to keep consumers safe.

NPA supports the position that consumers should consult their physician any time they are supplementing their diet, making a change in their diet, or seeking advice on a medication. A more important focus for this consumer update would have been to emphasize the importance of talking with a doctor before starting any medication or dietary supplement or making any changes to one's health care regimen.

NPA asks that you please clarify the inaccuracies in this piece so that consumers can be better educated on the topic at hand.

Sincerely,

Lauren Cohen
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[2] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

From:	Strambler, Karen
To:	Welch, Cara
Cc:	Zajac, Andrew J; Assar, Carrie
Subject:	RE: Meeting Request with NPA re: Carrageenan Advisory Committee
Date:	Thursday, May 19, 2016 9:16:41 AM
Attachments:	image003.png image004.png

Sure, I am happy to participate.

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:16 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Thanks. Should you be involved in a meeting with NPA?

From: Strambler, Karen
Sent: Thursday, May 19, 2016 9:15 AM
To: Welch, Cara
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Cara,

I think you should meet with NPA to find out what issues they would like an advisory committee to address. We can talk after you meet with them so I can provide you with information on the advisory committee process.

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:05 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
I have time today to discuss but I don't have anything to discuss…that is, I don't know what their concerns are ☺
If you want to chat, can you give me a call sometime this afternoon? (2-2333)
Thanks
Cara

From: Strambler, Karen
Sent: Thursday, May 19, 2016 8:58 AM
To: Welch, Cara
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

I don't see a problem with forming a subcommittee to address their concerns. Are you available today to discuss this topic?

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 8:49 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: FW: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
OFAS, ONFL, and ODSP were contacted by the Natural Products Association for a meeting request re: Carrageenan. At this point, (b) (5), since I'm not aware of dietary supplement concerns with carrageenan. Since you're the food advisory committee federal officer, I wanted to get your opinion on the request.
Thanks
Cara

From: Michael Kelley [mailto:mkelley@npainfo.org]
Sent: Thursday, May 12, 2016 12:07 PM
To: Assar, Carrie; Mattia, Antonia; Welch, Cara; Mozersky, Robert
Cc: Daniel Fabricant, Ph.D.; Corey Hilmas
Subject: Meeting Request with NPA re: Carrageenan Advisory Committee

Good Afternoon-

Mike Kelley with the NPA here. I hope this email finds you all well.

NPA would like to request a meeting to discuss adding Carrageenan to the list of current FDA Advisory Committees. Could you let me know if there a specific date and time that works for your team in the coming weeks?

Thank you in advance,

Mike

Michael Kelley
Director, Government Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office: (202) 204-4720
Cell: (703) 509-7052
www.NPAinfo.org

From:	Strambler, Karen
To:	Welch, Cara
Cc:	Zajac, Andrew J; Assar, Carrie
Subject:	RE: Meeting Request with NPA re: Carrageenan Advisory Committee
Date:	Thursday, May 19, 2016 9:15:14 AM
Attachments:	image003.png image004.png

Cara,

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Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:05 AM
To: Strambler, Karen
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Sent: Thursday, May 12, 2016 12:07 PM
To: Assar, Carrie; Mattia, Antonia; Welch, Cara; Mozersky, Robert
Cc: Daniel Fabricant, Ph.D.; Corey Hilmas
Subject: Meeting Request with NPA re: Carrageenan Advisory Committee

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Mike

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Office: (202) 204-4720
Cell: (703) 509-7052
www.NPAinfo.org

From:	Strambler, Karen
To:	Welch, Cara
Cc:	Zajac, Andrew J; Assar, Carrie
Subject:	RE: Meeting Request with NPA re: Carrageenan Advisory Committee
Date:	Thursday, May 19, 2016 8:57:34 AM
Attachments:	image003.png image004.png

Hi Cara,

I don't see a problem with forming a subcommittee to address their concerns. Are you available today to discuss this topic?

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 8:49 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: FW: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
OFAS, ONFL, and ODSP were contacted by the Natural Products Association for a meeting request re: Carrageenan. At this point (b) (5), since I'm not aware of dietary supplement concerns with carrageenan. Since you're the food advisory committee federal officer, I wanted to get your opinion on the request.
Thanks
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From: Michael Kelley [mailto:mkelley@npainfo.org]
Sent: Thursday, May 12, 2016 12:07 PM
To: Assar, Carrie; Mattia, Antonia; Welch, Cara; Mozersky, Robert
Cc: Daniel Fabricant, Ph.D.; Corey Hilmas
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Thank you in advance,

Mike

Michael Kelley
Director, Government Affairs

From:	Assar, Carrie
To:	Harry, Molly; Welch, Cara
Cc:	Strambler, Karen; Honigfort, Mical
Subject:	RE: Meeting Request with NPA re: Carrageenan Advisory Committee
Date:	Friday, July 01, 2016 11:35:22 AM
Attachments:	image003.png image004.png

Cara,

IFMFS is happy to participate in the internal discussion as well. Currently, (b) (5) JECFA's conclusion in their 2015 technical report that states ""the use of carrageenan in infant formula or formula for special medical purposes at concentrations up to 1000 mg/L is not of concern." This level is higher than what we see in US infant formulas.

Carrie

From: Harry, Molly
Sent: Friday, July 01, 2016 11:25 AM
To: Welch, Cara
Cc: Strambler, Karen; Assar, Carrie; Honigfort, Mical
Subject: FW: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

OFAS has reviewed the safety of food-grade carrageenan extensively and we have no safety issues with its use in food. There are regulations in the CFR permitting the safe use of carrageenan, and available safety data continue to support its safe use. We do not see the need for holding an FAC meeting at this time on this subject. OFAS does not have any questions related to carrageenan that we need to find answers for regulatory purposes. We will be glad to participate in the internal discussion late next week on the subject.

Thanks, Molly

From: Welch, Cara
Sent: Thursday, June 30, 2016 4:59 PM
To: Strambler, Karen
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

I'm comfortable discussing the possibility but (b) (5). We haven't heard much on Carrageenan from our stakeholders. We can definitely push the discussion to late next week ☺
Thanks for the quick response
Cara

From: Strambler, Karen

Sent: Thursday, June 30, 2016 4:50 PM
To: Welch, Cara
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

Did you want to discuss the possibility of holding a Food Advisory Committee meeting to addressing Carrageenan? If we hold the meeting we could add individuals to the committee, who have expertise on topic. Please let me know how you would like to proceed. I will be out of the office on tomorrow but returning on Wednesday, July 6.

Thanks,
Karen

From: Welch, Cara
Sent: Thursday, June 30, 2016 4:39 PM
To: Strambler, Karen
Cc: Harry, Molly; Honigfort, Mical; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Karen,
Molly, Carrie, and I met with NPA on Monday to discuss convening a Food Advisory Committee on Carrageenan. Molly and Carrie are much more knowledgeable on the ingredient (b) (5) . (b) (5) However, JECFA recently confirmed the safety of Carrageenan (I think?) and OFAS as well as Infant Formula seem to be comfortable with Carrageenan in foods/infant formula. I think (b) (5) .

I'm curious Molly, Mical, and Carrie's impressions on the desire/need for an AC on carrageenan.

Thanks
Cara

From: Strambler, Karen
Sent: Thursday, May 19, 2016 3:59 PM
To: Welch, Cara
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

I spoke to Susan Bernard about this and no need include me in the meeting with NPA but we can talk after you meet them.

Thanks.

Karen

From: Welch, Cara
Sent: Thursday, May 19, 2016 9:16 AM
To: Strambler, Karen
Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Thanks. Should you be involved in a meeting with NPA?

From: Strambler, Karen
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To: Welch, Cara
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Karen

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I have time today to discuss but I don't have anything to discuss…that is, I don't know what their concerns are ☺
If you want to chat, can you give me a call sometime this afternoon? (2-2333)
Thanks
Cara

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Cc: Zajac, Andrew J; Assar, Carrie
Subject: RE: Meeting Request with NPA re: Carrageenan Advisory Committee

Hi Cara,

I don't see a problem with forming a subcommittee to address their concerns. Are you available today to discuss this topic?

Karen

From:	Tave, Steven
To:	Welch, Cara
Subject:	RE: NPA and caffeine
Date:	Monday, November 07, 2016 4:15:50 PM

Thanks!

From: Welch, Cara
Sent: Monday, November 07, 2016 4:14 PM
To: Tave, Steven
Subject: RE: NPA and caffeine

In the press, yes. I'm not aware there is an association position on it.

http://www.npr.org/sections/health-shots/2014/12/31/371692640/potent-powdered-caffeine-raises-safety-worries

But Daniel Fabricant, executive director of the Natural Products Association, says the problem is not with the product, but with people misusing it.

"It is the dosage that makes anything a poison," Fabricant says. "Take water for example, [or] salt for example — if you use too much, it creates problems. I think that's really the issue here. People safely use caffeine every day."

http://www.naturalproductsinsider.com/blogs/insider-law/2015/09/fda-issues-warning-letters-on-powdered-caffeine.aspx

Daniel Fabricant, Ph.D., executive director and CEO of the Natural Products Association (NPA), said pure powdered caffeine is a legal dietary ingredient.

"I am unfamiliar with empirical evidence at FDA or elsewhere that would suggest that people would substitute directed conditions of use (i.e., greater than 1/16th of a teaspoon) due to measuring devices that weren't consistent with the labeling," Fabricant advised FDA officials Tuesday in an email. "Furthermore, the ability to weigh out 1/16th and 1/32nd of a teaspoon is commonplace in conventional culinary arts as explained by" online references that Fabricant provided the officials.

In a phone interview Tuesday, Fabricant expressed concerns that FDA's reasoning in the warning letters could have broader implications.

"They are saying people can't be trusted to measure things out" without the studies or data to support that idea, said Fabricant, who previously led FDA's Division of Dietary Supplement Programs. "If they can use that argument here, they can certainly use that on other products that contain caffeine and are used safely by millions of Americans every day."

If a person takes one-sixteenth of a teaspoon of powdered caffeine, the amount is "well under anything that any scientific body has said is harmful," Fabricant added.

Others in the industry—including the American Herbal Products Association (AHPA), Council for Responsible Nutrition (CRN) and United Natural Products Alliance (UNPA)—have adopted policies and guidelines that discouraged the sales of powdered caffeine to consumers by their members.

http://www.nutraingredients-usa.com/Regulation/NPA-s-Fabricant-on-caffeine-We-don-t-want-to-get-into-a-position-where-Senators-are-using-a-court-of-public-opinion-to-regulate-the-industry
[NutraIngredients doesn't allow you to copy/paste directly from the article but the quote is more about the problem being people misusing the product.]

http://wshu.org/post/fda-calls-powdered-caffeine-unsafe

Dr. Daniel Fabricant, CEO of the Natural Products Association, said he doesn't agree with the FDAs claims against the powdered caffeine companies.

"We certainly respect the FDA's response and opinions and we understand the concerns surrounding pure powdered caffeine," Fabricant said. "I think the agency is missing its target claiming the product is dangerous because it can't be measured. They're not actually claiming the product is dangerous."

Fabricant said consumers shouldn't have a problem measuring out one-sixteenth of a teaspoon, regardless of how small it is. And the fact that two men overdosed isn't enough evidence that powdered caffeine is unsafe to use.

"It's a tragic reminder of an iron clad rule when it comes to these issues, which is to always read labels carefully on anything you put in your body and always consult a doctor or your health care provider when using any over-the-counter medicine or dietary supplement," he said.

From: Tave, Steven
Sent: Monday, November 07, 2016 4:10 PM
To: Welch, Cara
Subject: NPA and caffeine

Do you know if NPA has made any statements on the record about powdered caffeine as a dietary supplement?

Steven J. Tave
Acting Director
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
(301) 796-8608 (office)
(202) 631-1427 (blackberry)
steven.tave@fda.hhs.gov

From: Tave_Steven
To: Welch_Cara; Durkin_Robert
Subject: RE: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source
Date: Thursday, January 12, 2017 12:13:27 PM

Here's really into the phrase "binding norm," isn't he?

From: Welch, Cara
Sent: Thursday, January 12, 2017 11:52 AM
To: Tave, Steven; Durkin, Robert
Subject: FW: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/NPA%20Letter%20to%20President-Elect%20Trump.pdf

---

From: NutraIngredients-USA [mailto:newsletter@nutraingredients-usa.com]
Sent: Thursday, January 12, 2017 11:23 AM
To: Welch, Cara
Subject: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

TODAY'S HEADLINES

NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods onboard

The Natural Products Association has officially launched the Supplement Safety and Compliance Initiative (SSCI), with some of the largest retailers of natural products and supplements involved... Read

FTC outlines lessons for MLMs following Herbalife and Vemma cases

The Federal Trade Commission has released guidance for MLMs based on lessons learned from the FTC's cases against Herbalife and Vemma... Read

NPA outlines top supplement-related legislative issues for PEOTUS Trump

NDIs, kratom, maternal and child nutrition, medical foods, health claims, and reducing the cost of healthcare are among the important issues affecting dietary supplements and the natural products industry in 2017, according to the Natural Products Association. .. Read

Sabinsa study supports DigeZyme's benefit in relieving post-exercise soreness

Sabinsa's researchers in Bangalore, India, found that the branded multi-enzyme complex ingredient DigeZyme improved the outcome measures related to delayed onset muscle soreness after exercise, compared to placebo... Read

Heard of the gut-brain axis? Meet the gut-skin axis...

Probiotic supplementation may improve adult acne appearance as researchers discuss the existence of a gut-skin axis in which the gastrointestinal area is targeted by bacterial strains to affect skin physiology... Read

Aquatic plant potential: Why duckweed could become a source of protein and omega-3 beyond South East Asia

Duckweed has long been consumed as an inexpensive protein and source of omega-3 in several South East Asia countries, but now researchers are questioning if it has the potential to be adopted by south Asian and even Western consumers too... Read

All News Headlines for: January December November

EDITOR'S CHOICE

Marketers of Prevagen charged with making false and unsubstantiated claims by FTC, NY AG

Quincy Bioscience, marketers of brain health product Prevagen, has been charged with making deceptive memory, cognitive improvement claims by the Federal Trade Commission and New York State Attorney General... Read

Raising the bar: CRN and IPA release best practice guidelines for probiotics

New best practices guidelines for the labeling, storing, and stability testing for probiotic products will facilitate transparency and consistency in the US probiotics sector... Read

UPCOMING **LIVE WEBINARS**

Balancing Innovation and Risk in Sports Nutrition Ingredients

08-Feb-2017

Sports nutrition supplements are one of the fastest growing and most innovative categories in the dietary supplement industry, but this growth and innovation can create s...

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GLOBAL INDUSTRY NEWS

Reducing sodium intake could save more lives, money than treating related disease, study finds

Ambitious sodium reduction targets for the next two and 10 years laid out by FDA in draft voluntary guidance released last summer not only could save lives, but they could generate huge cost savings based on new research published this week in The BMJ. .. Read

KitoZyme banking on novel prebiotic with new medical device platform

Belgian firm KitoZyme is planning a roll out of of medical device products that put restoring gut flora at centre stage, company told Nutraingredients after receiving two new certifications... Read

DATELINE SOUTHEAST ASIA

Indonesia hints at halal mark, urges firms to target Islamic market

Plus: Hanoi ramps up local agri-inspections due to lack of safe local food; and El Niño disruption causes palm kernel prices to double... Read

Chicory extract found to improve memory loss in mice: China study

Chicoric acid (CA), a nutraceutical component from the chicory plant could slow down memory loss associated with Alzheimer's and other neurodegenerative diseases, a study revealed... Read

PREVIOUS HEADLINES

» Bulletin highlights adulteration issues for St. John's wort

» Ayurveda extract helps reduce knee pain in elderly: Sabinsa Japanese RCT

» NutraIngredients Awards 2017: Deadline is 3 February

» 'Government recommendation is clear': Statement published in JAMA supports folic acid supplementation for healthy pregnancy

» Danone-Nutricia RCT backs 'toddler milk' for improved iron & vitamin D status

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CPA Recruitment Ltd / Providence

Operations Management Training Internship Program - Summer 2017
Nestle / Los Angeles AFB

Warehouse Operations Supervisor - Atanta Syrup Plant
Coca Cola / Atlanta

Quality Assurance Manager
Barry Callebaut / United States

Gfo Eea Payroll Project Analyst
Coca Cola - Europe / Drogheda

SEARCH JOBS

RELATED PRODUCTS

- The Advantage of Outsourcing Fermentation-based Manufacturing Processes - Evonik Health Care
- The NutraIngredients-USA Pre-&Probiotics forum - William Reed Business Media
- Healthy Living for Consumers: Trends, Challenges and Innovative Dose Forms - Catalent Pharma Solutions
- What Is the Most Bioavailable, Organic Form of Magnesium? - Albion
- Bioavailable and Stable Ubiquinol CoQH-CF Softgels - Soft Gel
- Aronox® – powerful, natural heart health benefits - Naturex
- Pioneering probiotics application in the Brain-Gut axis - Lallemand Health Solutions: your probiotic solutions provider
- US CONSUMERS INTERESTED IN FIBER TO IMPROVE HEALTH - Sensus
- Patented Lychee Extract for Sports Nutrition and RTD Applications - Maypro Industries
- UC-II® Joint Health Gummies - InterHealth Nutraceuticals, Inc.
- Strategic Nutrition for Eye Health - Fortitech Premixes, by DSM

élantria™ - A New Standard In Stability for Omega-3 - PLT Health Solutions

AlaskOmega® leads the omega-3 concentrate market in Freshness - AlaskOmega

Pycnogenol® Helps Curb Muscle Loss Due to Aging - Horphag Research (USA) Inc.

Find our NutraingredientsUSA team on:

From: Tave, Steven
To: Welch, Cara; Durkin, Robert
Subject: RE: NPA Thursday Roundup
Date: Friday, December 22, 2017 1:30:55 PM

Also, proofreading is overrated.

From: Welch, Cara
Sent: Friday, December 22, 2017 1:21 PM
To: Tave, Steven <Steven.Tave@fda.hhs.gov>; Durkin, Robert <Robert.Durkin@fda.hhs.gov>
Subject: FW: NPA Thursday Roundup

But seriously, the excitement in this email is almost palpable. LOL

"first again, first ever" (2nd story down) and then "First Event Partner to the Second Iteration of The Big Natural" (~6th story down?).

From: Joel and Cara Welch
Sent: Friday, December 22, 2017 11:18 AM
To: Welch, Cara <Cara.Welch@fda.hhs.gov>
Subject: Fwd: NPA Thursday Roundup

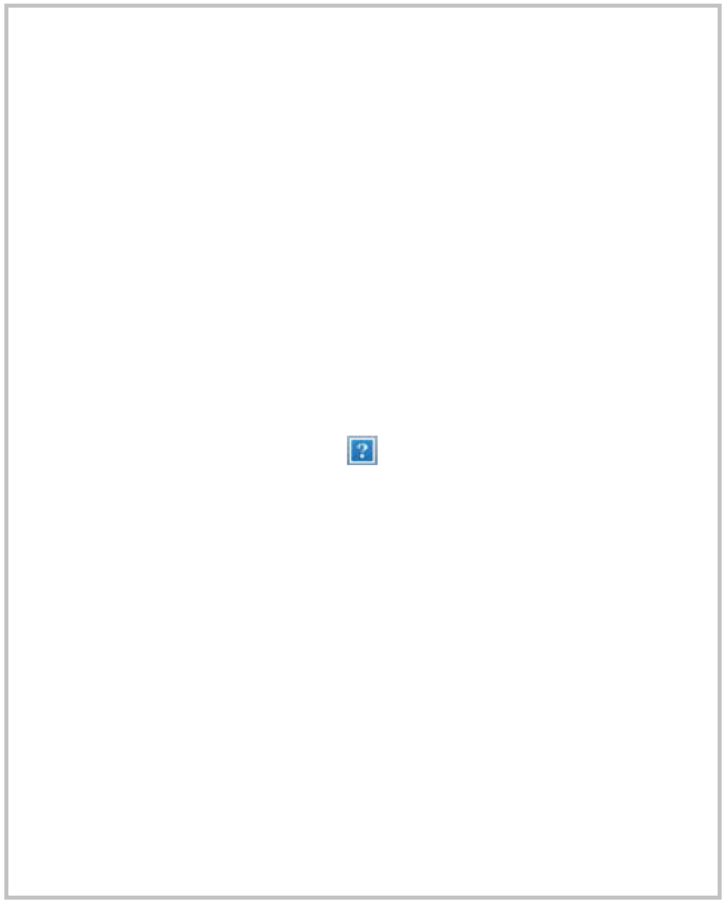
---------- Forwarded message ----------
From: **Dr. Daniel Fabricant** <daniel.fabricant@npanational.org>
Date: Thu, Dec 21, 2017 at 3:59 PM
Subject: NPA Thursday Roundup
To: (b) (6)

View web version

December 21, 2017

NPA Meets with OMB to Discuss the Nutrition and Supplement Facts Labeling Final Rule

Last week, Dr. Fabricant met with OMB to discuss the nutrition and supplement facts labeling final rule. A very important matter given that the industry has to spend $200 million to made label changes. The unduly, burdensome changes seen in the final rule now require dietary fibers firms to do 2 RCTs (Random Clinical Trials) to show a beneficial physiological effect. In addition, the eye tracking studies, designed to support some of the new changes like added sugars, do not support FDA's position in this final rule. Furthermore, the FDA failed to submit an economic impact analysis with the guidance to OMB regarding this new cost burden to the food and supplement industry. If the Agency is implementing such burdensome changes, they must first provide material evidence in the form of substantiated consumer studies, which serves as the basis for the labeling changes. Therefore, NPA is requesting a 3 year extension in the compliance date for the final rule, as it provides sufficient time for the agency to conduct proper empirical studies involving consumer research and will allow for accurate and consistent changes to be made, without crippling costs to business that will be passed on to all American consumers.



NPA and Their Members Are First Again, First Ever Request of Its Kind (Using the IFR on Reduced ID Testing) Submitted on Behalf of Bergstrom Nutrition

A request made on behalf of Bergstrom Nutrition by the Natural Products Association (NPA) to the Food

and Drug Administration (FDA) could lead to lower costs for consumers and the federal government and increase the overall quality of nutritional supplements. This is the first time a manufacturer has submitted a Citizen Petition requesting a reduction in identity testing while showing no diminution in product quality, based upon their historical record of demonstrating high quality.

Click here for the news release and the Citizen Petition.

NPA Makes a Statement on NBC's Nightly News Regarding FDA's Draft Guidance on "Drug Products Labeled as Homeopathic"

FDA says it will crack down on homeopathic products. NPA responds.

Click here to watch the video.

Dan Fabricant on Leadership in Action

Dan Fabricant was interviewed on Business Radio's *Leadership in Action* on Sirius XM.

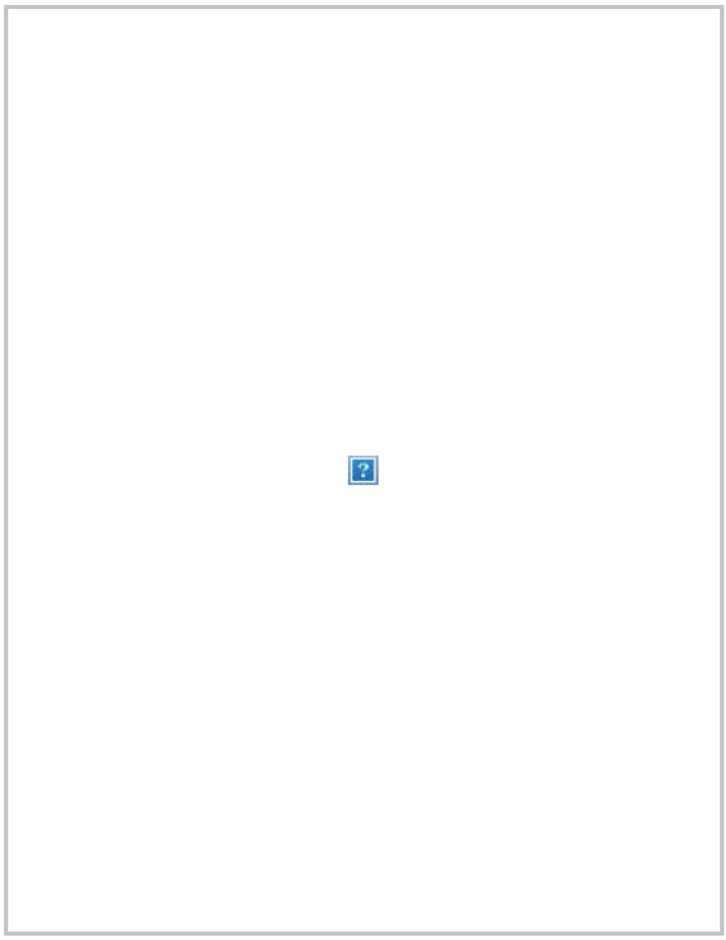
Click here to listen to the interview.

Register for Natural Products Day 2018

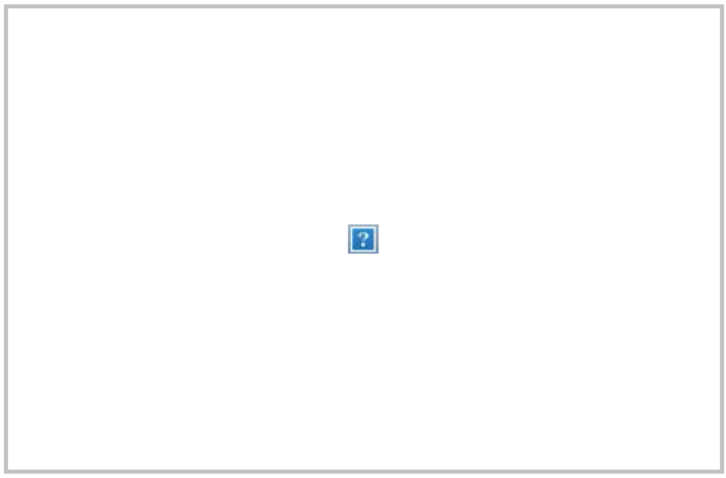
Each year, the natural products industry gathers in our nation's capital to educate members of Congress and legislative staff about the important role natural products play in keeping Americans healthy and the overwhelming public benefits of preventive care. This day-long advocacy conference is hosted each year by NPA to provide retailers, suppliers, and all industry stakeholders from across the country with the opportunity to become lobbyists for a day.

There is no registration cost to attend and all meetings will be arranged by NPA.

For questions and registration, email Natural@NPAnational.org



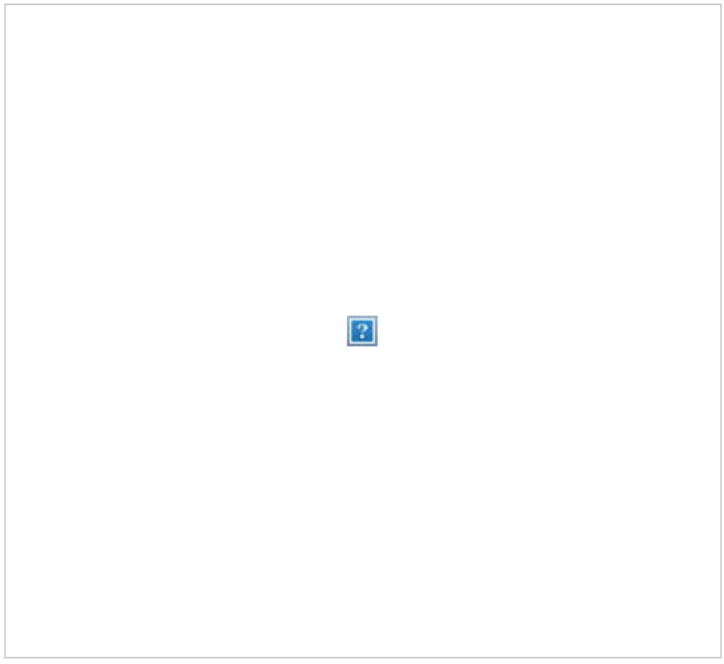
The Natural Products Association Would Like to Welcome Our First Event Partner to the Second Iteration of The Big Natural



We are pleased to be joined by Ronie Schmelz of Tucker Ellis LLP! Ronie will be joining us as a moderator for one of the Government Spotlight Discussions.

Offering 2 days of industry-driven educational sessions, including interactive discussions, case studies and valuable benchmarking and networking opportunities, The Big Natural is the only event that will put you in the same room with industry leaders who are currently driving innovation in the natural products industry. Only a limited number of spaces will be made available for program sponsors in the legal and business innovation track sessions. To learn more about how to get involved as a sponsor, contact Danielle Gonzalez at Danielle@Momentumevents.com.

NPA Pre-DSHEA ODI Book Orders Are Rolling In Reserve Your Copy Today



A new book from NPA compiles the first ever list of pre-DSHEA dietary ingredients. The NPA book, titled Pre-DSHEA List of Old Dietary Ingredients, is available for pre-sale until the end of the year for both members, non-members, federal agencies and non-governmental organizations (NGOs).

"This book is the first of its kind and should serve as a valuable tool for industry regulatory divisions, retailers, industry consultants, as well as state and federal regulators," said Dan Fabricant, Ph.D., President and CEO of NPA and one of the book's authors. "NPA continues to work with the FDA in their quest to develop a list of its pre-DSHEA dietary ingredients that are exempt from notification. This book represents a considerable investment of NPA's resources and took over 2 years to develop. We look forward to releasing new editions of the book as we add new independently verified ingredients to this extensive collection."

PRE-ORDER YOUR COPY NOW

Tell Congress TODAY to Cosponsor H.R. 3529 - the "WIC Improvement Act"

Representative Dave Brat (R-VA) recently introduced H.R. 3529, the "WIC Improvement Act," for the

inclusion of multivitamins for purchase as part of the special supplemental nutrition program for women, infants, and children (WIC). The WIC program provides Federal grants to States for supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age 5 who are found to be at nutritional risk. The program has grown significantly in its nearly 40-years of existence, and it now serves approximately 8 million participants.

The "WIC Improvement Act" will expand WIC to give these low-income families equal opportunity for access to low-cost, high nutrient alternatives, like multivitamins. Multivitamins are proven to have many health benefits especially relevant to those the WIC program intends to help:

- Classic nutrient deficiency diseases (scurvy, pellagra, and iron deficiency anemia)
- Improve appetite and growth rates
- Prevent neural tube birth defects
- Protect against heart disease and stroke
- Build bone mass in young children

The "WIC Improvement Act" will help provide relief to the 25 million Americans currently living in "food deserts." The United Stated Department of Agriculture (USDA) defines a food desert as: parts of the country vapid of fresh fruit, vegetables, and other healthful whole foods, usually found in impoverished areas. With your support, millions of Americans will be able to provide healthier lives to their families.

Tell your Representative TODAY to cosponsor H.R. 3529.

TAKE ACTION NOW

Stevia Included in Philadelphia Soda Tax

The City of Philadelphia has recently passed the Sugar-Sweetened Beverage Tax or the "Soda Tax," which took effect January 1, 2017. Within this newly enacted legislation, stevia was included as a part of the artificial sugar substitutes that should be taxed. However, as you may know, stevia is a natural plant-derived sweetener and therefore should not be included. Since the tax has been implemented, beverage prices have seen the following increases:

- 20-ounce drink that used to cost $1.99 is now $2.29
- 64-ounce jug of juice at $2.39 is now $3.35
- 6 pack of diet green tea at $4.99 is now $6.07

In the "Soda Tax" all distributors and dealers pay $.015 per ounce of sweetened beverage, and as taxes get added, the cost often gets passed downstream ultimately to the consumer.

Write Frank Breslin, Commissioner of Department of Revenue, TODAY to tell him that stevia should not be included in the Sugar-Sweetened Beverage tax.

TAKE ACTION NOW

Natural Products Association
440 1st Street NW, Suite 520, Washington, DC 20001
Visit our website | Contact Us

From: Callahan, John
To: Welch, Cara; Bunning, Vincent
Cc: CFSAN ORS DIV DIRS
Subject: RE: NPA webinar
Date: Thursday, March 12, 2015 9:42:20 AM

This is a person that Andrea Ottessen is bringing on board for 6 months, to utilize his expertise in DNA and to bring him up to speed on metagenomics (microbial). (b) (5) there as well. There was also thought that (b) (5), as needed. However, (b) (5). I was not aware that he was on board yet through ORISE, so I think that anything he does with NPA is as a Smithsonian employee. However, let me check with Andrea.
John

John H. Callahan, Ph.D.
Acting Deputy Director, Office of Regulatory Science
FDA/Center for Food Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway
2D-043/HFS-707
College Park, MD 20740
240-402-2039/Blackberry 301-221-1795
FAX 301-436-2624
John.callahan@fda.hhs.gov

From: Welch, Cara
Sent: Thursday, March 12, 2015 8:44 AM
To: Bunning, Vincent
Cc: CFSAN ORS DIV DIRS
Subject: RE: NPA webinar

David Erickson, a Ph.D. botanist, geneticist, and biologist at the Smithsonian National Museum of Natural History. He currently serves as the Food and Drug Administration's (FDA) outside expert consultant on DNA barcoding through an FDA ORISE Fellowship, where he is collaborating on experiment testing methods of validation for FDA-regulated food products, including dietary supplements.

I guess maybe he's not in ORS but I thought Sara and Jon mentioned an ORISE coming on soon specifically with DNA projects.

From: Bunning, Vincent
Sent: Thursday, March 12, 2015 8:42 AM
To: Welch, Cara
Cc: CFSAN ORS DIV DIRS
Subject: Re: NPA webinar

Who is it?

From: Welch, Cara
Sent: Thursday, March 12, 2015 08:40 AM Eastern Standard Time
To: Bunning, Vincent
Subject: NPA webinar

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http://www.npainfo.org/NPA/EducationCertification/Weds_Webinars/DNA_Methodology_Webinar.aspx

Join the Natural Products Association (NPA) on **Wednesday, March 18 at 2:00 p.m. EST** for an all-new webinar featuring a discussion with scientists from the Smithsonian National Museum of Natural History and ChromaDex. These experts in their field of DNA barcoding will discuss its utility for authentication in dietary supplement raw ingredients, processed ingredients and finished products. During ***DNA Methodology for Authentication and Other Applications for Foods and Dietary Supplements***, our speakers will provide a broad overview on the different commodities that DNA barcoding and sequencing is used for, and then turn the discussion to when it can be applied for testing raw botanical materials. Our speakers will then address if/whether it is appropriate to be used for extracts of raw botanical materials or even for finished foods and dietary supplement products.

The webinar features **David Erickson, a Ph.D.** botanist, geneticist, and biologist at the Smithsonian National Museum of Natural History, where he co-authored 50 peer reviewed published manuscripts using DNA barcoding methods. Dr. Erickson is a leading authority on the application of DNA barcoding for species authentication. He currently serves as the Food and Drug Administration's (FDA) outside expert consultant on DNA barcoding through an FDA ORISE Fellowship, where he is collaborating on experiment testing methods of validation for FDA-regulated food products, including dietary supplements.

Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Bunning, Vincent
To: Welch, Cara
Subject: Re: NPA webinar
Date: Thursday, March 12, 2015 8:52:22 AM

Investigating! Get back to you!

From: Welch, Cara
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Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From:	Bunning, Vincent
To:	Brown, Eric; Callahan, John; Welch, Cara
Cc:	CFSAN ORS DIV DIRS
Subject:	Re: NPA webinar
Date:	Thursday, March 12, 2015 10:00:38 AM

Is he on board yet?

From: Brown, Eric
Sent: Thursday, March 12, 2015 09:44 AM Eastern Standard Time
To: Callahan, John; Welch, Cara; Bunning, Vincent
Cc: CFSAN ORS DIV DIRS
Subject: Re: NPA webinar

As am I.
Eric Brown, Ph.D.
Supervisory Microbiologist
CFSAN/FDA
College Park, MD 20740
Bberry: 301-503-0508

"This message was sent from a
Blackberry"

From: Callahan, John
Sent: Thursday, March 12, 2015 09:42 AM
To: Welch, Cara; Bunning, Vincent
Cc: CFSAN ORS DIV DIRS
Subject: RE: NPA webinar

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John H. Callahan, Ph.D.
Acting Deputy Director, Office of Regulatory Science
FDA/Center for Food Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway
2D-043/HFS-707
College Park, MD 20740
240-402-2039/Blackberry 301-221-1795
FAX 301-436-2624
John.callahan@fda.hhs.gov

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Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From:	Salem, Scarlett
To:	Welch, Cara; Olson, Eric; Swift, Sibyl; Assar, Samir
Subject:	RE: RFP"s for NPA
Date:	Friday, October 13, 2017 3:45:33 PM

Would this be what they are looking for re: WCFS?
https://www.fda.gov/Food/NewsEvents/FoodSafetyGrants/ucm358538.htm

---

From: Welch, Cara
Sent: Friday, October 13, 2017 1:22 PM
To: Olson, Eric <Eric.Olson@fda.hhs.gov>; Swift, Sibyl <Sibyl.Swift@fda.hhs.gov>; Assar, Samir <Samir.Assar@fda.hhs.gov>; Salem, Scarlett <Scarlett.Salem@fda.hhs.gov>
Subject: RE: RFP's for NPA

Sure, this is the Natural Products Association, Dan Fabricant's trade group re: dietary supplements.

Aren't these documents public?

From: Olson, Eric
Sent: Friday, October 13, 2017 12:38 PM
To: Welch, Cara <Cara.Welch@fda.hhs.gov>; Swift, Sibyl <Sibyl.Swift@fda.hhs.gov>; Assar, Samir <Samir.Assar@fda.hhs.gov>; Salem, Scarlett <Scarlett.Salem@fda.hhs.gov>
Subject: FW: RFP's for NPA

FYI, I'll follow up with Christine but do you know this group?

From: Christine Yeo [mailto:cyeo@npanational.org]
Sent: Friday, October 13, 2017 11:40 AM
To: Olson, Eric <Eric.Olson@fda.hhs.gov>
Subject: RFP's for NPA

Hi Eric,

Thank you for taking the time to speak with me this morning. I am looking for the Request for Proposal of University of Mississippi's and UC Davis' Centers of Excellence. Thank you for your help.

Kindly,
Christine Yeo, Regulatory Affairs Assistant
Natural Products Association
cyeo@npanational.org
Direct Ph. 202.223.0101 ext. 111
Fax Ph. 202.223.0250
440 First Street NW, STE 520
Washington, D.C. 20001

From:	Mary Allison
To:	Welch, Cara
Subject:	Speaking Opportunities | NPA"s The Big Natural
Date:	Wednesday, March 22, 2017 10:08:41 AM

Dear Cara,

Join us June 7-9, 2017 at the LINQ in Las Vegas for the Natural Products Association's The Big Natural, an executive forum uniting retailers, investors, ingredient suppliers, investors and manufacturers within the health, and wellness, dietary supplements, and food, beverage and CPG industries. Specifically addressing the unique needs of executive leadership and department heads, The Big Natural, is an ideal venue to highlight how you are impacting this quickly evolving industry advance its business.

Sponsorship opportunities are limited and range from thought leadership to social hosting for this event. If you are interested in building relationships that lead to business, then I would love to discuss securing one of these coveted sponsorship opportunities for your company.

Sincerely,

Mary Allison
Director Business Development & Client Relations
Momentum | 917.655.3304

From: NutraIngredients-USA
To: Welch, Cara
Subject: Working with contract labs / NPA shrinks board / Beauty-from-within rising / Common blood sugar claims pitfalls / ABC"s Blumenthal honored / Non GMO cert for rice ingredients
Date: Tuesday, February 28, 2017 12:54:33 PM

If you are unable to view this message correctly, click here

Access:
EU edition | APAC edition | Food Jobs

Breaking News on Supplements, Health & Nutrition - **North America**

28-Feb-2017

TODAY'S HEADLINES

More information is always better in working with analytical labs, service providers say

If there were one thing an analytical lab contractor could tell a client it might be similar to what a psychologist would tell a new patient: Don't be shy. Tell me everything... Read

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From: NutraIngredients-USA
To: Welch_Cara
Subject: FTC takes action against "all natural" claims / GMO labeling, insurance & enforcement top NPA"s wish list in DC / Sodium phosphate and caffeine have limited sprint benefits / Increasing red bell pepper carotenoid solubility / Vitafoods preview
Date: Thursday, April 14, 2016 12:24:19 PM

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From:	Benjamin, Dianne
To:	OC-OFVM-ExecSec; Welch, Cara
Cc:	Swift, Sibyl; Elkin, Ted
Subject:	FW: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Friday, February 06, 2015 12:30:41 PM
Importance:	High

All –

See the email trail. This correspondence should be logged into AIMS. Cara's draft must first be Center – cleared and we can discuss who should sign.

Looping in Ted.

Thank you –

Dianne

From: DeLancey, Siobhan
Sent: Friday, February 06, 2015 11:15 AM
To: Barrett, Kari; Benjamin, Dianne
Cc: Shapinsky, David
Subject: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Hi Diane and Kari,

Cara Welch (acting director of the Division of Dietary Supplement Programs) just forwarded this letter she received from the Natural Products Association regarding the announcement Monday by the NY Attorney General's office regarding their testing of dietary supplement products for ingredient verification using DNA sequencing technology.

I wasn't sure who to send this to for tracking and coordination of a response, so am including both of you here.

From: Welch, Cara
Sent: Friday, February 06, 2015 10:43 AM
To: DeLancey, Siobhan
Cc: Harper, Kristina; Elkin, Ted
Subject: FW: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Siobhan, this is the letter I rec'd from NPA re: the NY AG topic. I realize this isn't as timely as the press inquiries with 2 hour deadlines but eventually we'll have to respond.

Tina, just wanted to keep you in the loop as well. Let me know if you want to discuss this.

Cara

Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Thursday, February 05, 2015 5:53 PM
To: Welch, Cara
Cc: Harper, Kristina
Subject: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Lauren Cohen
Vice President, Public Relations & Communications
Natural Products Association
Washington, DC

February 5, 2015

Cara Welch
Acting Director
Division of Dietary Supplement Programs
Food and Drug Administration
College Park, MD

Dear Dr. Welch,

On Tuesday, February 3, New York State Attorney General Eric Schneiderman ordered four major retailers to stop selling store-brand herbal supplements. All four retailers have received cease-and-desist letters demanding that they halt the sales of these supplements because a third-party testing lab used DNA barcoding to identify botanical ingredients, listed on the label, through a type of "genetic fingerprinting", and discovered evidence to the contrary. A total of 19 out of the 24 products tested supposedly contained DNA that was either unrecognizable or from a plant other than what was claimed on the label.

The Natural Products Association and the dietary supplement industry as a whole are concerned about this issue on several levels. There is no question that DNA finger printing is a powerful tool for natural product authentication, including raw materials before extraction. The information provided

by the New York Attorney General fails to mention the listing of botanical extracts as dietary ingredients in these herbal supplement products. Botanical extracts involve the use of alcohol or other solvent to extract the final dietary ingredient from the source botanical. The use of DNA barcoding methodology on extracts of raw ingredients is neither a good, better, or best standard of practice in the dietary supplement industry.

We ask the Food and Drug Administration to opine on whether this DNA barcoding technology is appropriate, sensitive, specific and scientifically valid for routine use by the dietary supplement industry to definitely identify botanicals used as the starting source material to create botanical extracts. If it is not commonly used for extracts of raw botanicals in finished products to identify botanical sources, why is this methodology being given credibility at this time. The concern is that DNA will be sufficiently degraded during the extraction and manufacturing process that intact DNA markers specific to a particular botanical will not be detected. Therefore, is the technology fit for purpose in botanical identity with regard to routine use in dietary supplements containing botanical extracts?

Thank you for your attention to this important matter, and we hope the FDA can shed light on the scientific validity of this study.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org

From:	Vogtman, Holly
To:	Welch, Cara
Subject:	Natural Products Association Applauds Launch of Supplement OWL—Urges NPA members to explore how to get their dietary supplement labels in the online registry
Date:	Thursday, April 20, 2017 10:18:12 AM

View on the web.

For Immediate Release

Contacts:

CRN Holly Vogtman, 202-204-7665

NPA Justin Bartolomeo, 202-789-4365

Natural Products Association Applauds Launch of Supplement OWL
—Urges NPA members to explore how to get their dietary supplement labels in the online registry—

Washington, D.C., *April 20, 2017*—The Natural Products Association (NPA) today offered its enthusiastic support for the Supplement OWL, the new online dietary supplement registry launching in April. In making the announcement, NPA encouraged its members to learn more about how to enter their dietary supplements in the Supplement OWL and to add their product labels to the growing collection of products represented in this online library of the dietary supplement industry.

“This is another example of the industry working together to give consumers what they deserve: confidence to know the products they take each and every day are safe and beneficial. As part of our commitment to supporting the suppliers, manufacturers, consumers and regulators of the natural products industry, NPA offers our full support for this new and exciting initiative,” said NPA Executive Director & CEO Daniel Fabricant, Ph.D. “This is a project that NPA Chairman Mark LeDoux and I have been discussing since I was still at the FDA. We are already receiving positive feedback from early participants in the program, and we urge the rest of our members to get on board. The success of this initiative depends on strong participation from all corners of the natural products market and we expect the program to be a tremendous benefit to everyone involved.”

“The Supplement OWL is the result of a great deal of bold initiative, forethought and creative thinking by many in the industry. We appreciate that leaders at NPA and its members, like GNC, were involved early in the brainstorming process of what an industry-run registry might entail. Working with our partner, UL, and many

others in the industry, these leaders helped craft the early framework for the Supplement OWL," said Steve Mister, President & CEO of the Council for Responsible Nutrition (CRN). "We are delighted that NPA is urging its membership to participate in this effort."

The Supplement OWL will be live later in April with the release of the public interface of the registry (www.SupplementOWL.org). The Supplement OWLallows users to access the registry through the internet and to search product entries by brand name, ingredient, health category and a host of other options. The registry provides ingredient listings, serving sizes, a copy of the *Supplement Facts* box, and other information about the supplements. Participation in the registry is free and open to all marketers of legitimate dietary supplements sold in the United States.

"NPA was one of the early pioneers in assembling its members' labels through its TruLabel Program going back to the 1990s," Mister acknowledged. "Even before the online access and search capabilities offered by today's technology, the TruLabel program captured basic product details for NPA's members. Today, the Supplement OWL offers sort and search abilities and full online access for retailers and consumers to complete images of product labels."

"NPA will soon be announcing details of its new TruLabel testing program," Fabricant offered. "This component of TruLabel will strengthen the program and provide even more details and resources to increase the accuracy of product labeling and ingredient authenticity. As the Supplement OWL expands, we are hopeful that these test results can also be made part of the registry and help to inform retailers and consumers about products in the marketplace."

Mister agreed. "In addition to the basic label information stored in the Supplement OWL registry, additional fields of information in Tier 2 of the Supplement OWL will allow retailers to verify product labels with background materials and documentation uploaded to the registry.

Testing results from programs like TruLabel will be ideal for helping retailers decide which supplements they want in their stores," Mister explained.

A free webinar, "Getting Started with the Supplement OWL Dietary Supplement Product Registry," will be held on Wednesday, April 25 at 2 pm EDT to help companies learn more about getting their product labels into the Supplement OWL. More information about the webinar is available here.

Natural Products Association (NPA) is the trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. NPA has set numerous industry standards, such as dietary supplement Good Manufacturing Practices (GMPs), as well as a definition of natural for home care and personal care products. NPA, which represents over 2,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids, has led the charge to keep the natural products industry in business for 79 years. Visit www.NPAinfo.org.

The **Council for Responsible Nutrition (CRN)** , founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @crn_supplements and @wannabewell and on Facebook.

From:	Naum, Marianna
To:	Tave, Steven; Welch, Cara; Durkin, Robert
Subject:	RE: Dietary Ingredient Database - Natural Products Association
Date:	Wednesday, September 21, 2016 2:02:10 PM
Attachments:	image001.png

Absolutely not! I say we go out strong.

Marianna Naum, Ph.D.
Strategic Communications and Public Engagement Staff
Office of Foods and Veterinary Medicine
Food and Drug Administration
5001 Campus Drive, College Park, MD 20740, HFS-315
Phone: 240-402-2748
Cell: 240-731-0262
Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth

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From: Tave, Steven
Sent: Wednesday, September 21, 2016 2:02 PM
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Yes, as long as it doesn't cause you any concern.

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 2:01 PM
To: Tave, Steven; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Yes I think it makes a lot of sense and I would strongly recommend it! I am assuming you are game?

Marianna Naum, Ph.D.
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Phone: 240-402-2748
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From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:56 PM
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Thanks. Let's discuss whether it makes sense to quote me directly (it might – curious for your thoughts).

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 1:43 PM
To: Welch, Cara; Tave, Steven; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

I am ok with this –

Thanks,
Marianna

Marianna Naum, Ph.D.
Strategic Communications and Public Engagement Staff
Office of Foods and Veterinary Medicine
Food and Drug Administration
5001 Campus Drive, College Park, MD 20740, HFS-315
Phone: 240-402-2748
Cell: 240-731-0262
Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth

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From: Welch, Cara
Sent: Wednesday, September 21, 2016 1:41 PM
To: Tave, Steven; Naum, Marianna; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Just one comment to provide added context.

(b) (5)

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:30 PM
To: Naum, Marianna; Durkin, Robert; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

Here's my proposal. Thoughts/edits are welcome:

(b) (5)

From:	Tave, Steven
To:	Naum, Marianna; Welch, Cara; Durkin, Robert
Subject:	RE: Dietary Ingredient Database - Natural Products Association
Date:	Wednesday, September 21, 2016 2:01:33 PM
Attachments:	image001.png

Yes, as long as it doesn't cause you any concern.

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 2:01 PM
To: Tave, Steven; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

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Marianna

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From: Welch, Cara
Sent: Wednesday, September 21, 2016 1:41 PM
To: Tave, Steven; Naum, Marianna; Durkin, Robert

Subject: RE: Dietary Ingredient Database - Natural Products Association

Just one comment to provide added context.

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From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:30 PM
To: Naum, Marianna; Durkin, Robert; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

Here's my proposal. Thoughts/edits are welcome:

(b) (5)

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 12:52 PM
To: Tave, Steven; Durkin, Robert; Welch, Cara
Subject: FW: Dietary Ingredient Database - Natural Products Association

Hey guys,

Please see request below. (b) (5) ? On a side note- I am convinced we addressed this in the past but I cannot find that response for the life of me. Cara or Bob if you remember what I am referring to please HELP!

Thanks,

Marianna

Marianna Naum, Ph.D.
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From: Stephen Daniells [mailto:Stephen.DANIELLS@wrbm.com]
Sent: Wednesday, September 21, 2016 11:33 AM
To: Naum, Marianna
Subject: Dietary Ingredient Database - Natural Products Association

Hi Marianna,

I hope you're doing well. I was wondering if FDA has a comment about this initiative?

Thanks

Stephen

From: Justin Bartolomeo [mailto:jbartolomeo@hdmk.org]
Sent: Wednesday, September 21, 2016 10:11 AM
Subject: Dietary Ingredient Database - Natural Products Association

Natural Products Association

440 1st St, N.W., Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

NEWS RELEASE

For Immediate Release
September 21, 2016

Contact: Justin Bartolomeo
(202) 789-4365
jbartolomeo@hdmk.org

NPA Developing Massive Safe Harbor Dietary Ingredient Database for Industry Members in Response to NDI Draft Guidance

Will Work with FDA to Finalize in Near Future

WASHINGTON, D.C. – The Natural Products Association (NPA), the oldest and largest trade association representing the dietary supplement industry, announced today it is in the later stages of developing a comprehensive safe harbor list of pre-DSHEA dietary ingredients for the industry based largely on evidence from past media reports, advertising, and other public sources.

"NPA has a treasure trove of useful labels and label information dating back to the 1940s from our retailing magazines, which will be used as evidence of dietary ingredients sold in interstate commerce before October 15, 1994," said NPA CEO Dr. Daniel Fabricant. "There are industry lists from the late 1990s and NPA's own list from 1996. In short, we have the evidence FDA is seeking to make these determinations, and we look forward to engaging FDA on developing a safe harbor list. We cannot afford to sit on our hands any longer," added Dr. Fabricant.

"The most common question we get from our members is whether something is an old ingredient and therefore off-limits to FDA or a new dietary ingredient, which triggers the NDI notification process. While future dietary ingredients may be appropriately subjected to that process, we are developing a safe harbor list now for greater clarity as to exactly what ingredients fall safely into the approved category and can be used in products today."

Likewise, FDA's recent NDI guidance stated it was "unlikely to regard a listing in Herbs of Commerce [1992 edition] as being solely determinative of whether a dietary ingredient was marketed as such before October 15, 1994." "The 1992 Herbs of Commerce book includes house plants and herbs not intended for human consumption, so it was not recognized by FDA as an authoritative list of pre-DSHEA dietary ingredients. It also focuses on herbs and does not include the myriad of other dietary ingredients falling within the statutory boundaries of a dietary ingredient created by DSHEA," added Dr. Fabricant.

NPA hopes to complete the Safe Harbor database of dietary ingredients in the near future, and will engage FDA in the coming months on its methodology and evidence.

Natural Products Association

The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents over 1,400 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Visit www.NPAinfo.org.
Follow NPA on social media:

- Facebook: Natural Products Association and The Natural Seal
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- LinkedIn: Natural Products Association, Natural Products Group and Grassroots Action Network

Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

# # #

without prior notice.

From:	Tave, Steven
To:	Naum, Marianna; Welch, Cara; Durkin, Robert
Subject:	RE: Dietary Ingredient Database - Natural Products Association
Date:	Wednesday, September 21, 2016 1:55:35 PM
Attachments:	image001 png

Thanks. Let's discuss whether it makes sense to quote me directly (it might – curious for your thoughts).

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 1:43 PM
To: Welch, Cara; Tave, Steven; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

I am ok with this –

Thanks,
Marianna

Marianna Naum, Ph.D.
Strategic Communications and Public Engagement Staff
Office of Foods and Veterinary Medicine
Food and Drug Administration
5001 Campus Drive, College Park, MD 20740, HFS-315
Phone: 240-402-2748
Cell: 240-731-0262
Follow us on Twitter @FDAfood; @FDACosmetics; and @FDAanimalhealth

---

From: Welch, Cara
Sent: Wednesday, September 21, 2016 1:41 PM
To: Tave, Steven; Naum, Marianna; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Just one comment to provide added context.

(b) (5)

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:30 PM
To: Naum, Marianna; Durkin, Robert; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

Here's my proposal. Thoughts/edits are welcome:

(b) (5)

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 12:52 PM
To: Tave, Steven; Durkin, Robert; Welch, Cara
Subject: FW: Dietary Ingredient Database - Natural Products Association

Hey guys,

Please see request below. (b) (5) ? On a side note- I am convinced we addressed this in the past but I cannot find that response for the life of me. Cara or Bob if you remember what I am referring to please HELP!

Thanks,

Marianna

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From: Stephen Daniells [mailto:Stephen.DANIELLS@wrbm.com]
Sent: Wednesday, September 21, 2016 11:33 AM
To: Naum, Marianna
Subject: Dietary Ingredient Database - Natural Products Association

Hi Marianna,

I hope you're doing well. I was wondering if FDA has a comment about this initiative?

Thanks

Stephen

From: Justin Bartolomeo [mailto:jbartolomeo@hdmk.org]
Sent: Wednesday, September 21, 2016 10:11 AM
Subject: Dietary Ingredient Database - Natural Products Association

Natural Products Association

440 1st St, N.W., Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

NEWS RELEASE

For Immediate Release
September 21, 2016

Contact: Justin Bartolomeo
(202) 789-4365
jbartolomeo@hdmk.org

NPA Developing Massive Safe Harbor Dietary Ingredient Database for Industry Members in Response to NDI Draft Guidance

Will Work with FDA to Finalize in Near Future

WASHINGTON, D.C. – The Natural Products Association (NPA), the oldest and largest trade association representing the dietary supplement industry, announced today it is in the later stages of developing a comprehensive safe harbor list of pre-DSHEA dietary ingredients for the industry based largely on evidence from past media reports, advertising, and other public sources.

"NPA has a treasure trove of useful labels and label information dating back to the 1940s from our retailing magazines, which will be used as evidence of dietary ingredients sold in interstate commerce before October 15, 1994," said NPA CEO Dr. Daniel Fabricant. "There are industry lists from the late 1990s and NPA's own list from 1996. In short, we have the evidence FDA is seeking to make these determinations, and we look forward to engaging FDA on developing a safe harbor list. We cannot afford to sit on our hands any longer," added Dr. Fabricant.

"The most common question we get from our members is whether something is an old ingredient and therefore off-limits to FDA or a new dietary ingredient, which triggers the NDI notification process. While future dietary ingredients may be appropriately subjected to that process, we are developing a safe harbor list now for greater clarity as to exactly what ingredients fall safely into the approved category and can be used in products today."

Likewise, FDA's recent NDI guidance stated it was "unlikely to regard a listing in Herbs of Commerce [1992 edition] as being solely determinative of whether a dietary ingredient was marketed as such before October 15, 1994." "The 1992 Herbs of Commerce book includes house plants and herbs not intended for human consumption, so it was not recognized by FDA as an authoritative list of pre-DSHEA dietary ingredients. It also focuses on herbs and does not include the myriad of other dietary ingredients falling within the statutory boundaries of a dietary ingredient created by DSHEA," added Dr. Fabricant.

NPA hopes to complete the Safe Harbor database of dietary ingredients in the near future, and will engage FDA in the coming months on its methodology and evidence.

Natural Products Association

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Follow NPA on social media:

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- Twitter: NPA National and NPA Natural Seal
- LinkedIn: Natural Products Association, Natural Products Group and Grassroots Action Network

Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

# # #

From: Naum, Marianna
To: Tave, Steven; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association
Date: Wednesday, September 21, 2016 1:13:40 PM
Attachments: image001.png

Got it. Thanks!

Marianna Naum, Ph.D.
Strategic Communications and Public Engagement Staff
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---

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:13 PM
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

No. That is a different issue. I will draft something this afternoon.

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 1:12 PM
To: Welch, Cara; Tave, Steven; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Yes thank you that is what I was referring too!

So would ODSP be ok if we sent the following statement:

(b) (5)

Marianna Naum, Ph.D.
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---

From: Welch, Cara
Sent: Wednesday, September 21, 2016 1:06 PM
To: Naum, Marianna; Tave, Steven; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

(A) not sure it matters but the article just published (http://www.nutraingredients-usa.com/Regulation/NPA-to-develop-safe-harbor-list-for-dietary-ingredients/?utm_source=newsletter_daily&utm_medium=email&utm_campaign=21-Sep-2016&c=JVrveeSja5xUBM76qxDzwDAaADBhCaYp&p2=)
(B) I attached an email on a different (but similar) topic that has some language.

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 12:52 PM
To: Tave, Steven; Durkin, Robert; Welch, Cara
Subject: FW: Dietary Ingredient Database - Natural Products Association

Hey guys,

Please see request below. (b) (5) ? On a side note- I am convinced we addressed this in the past but I cannot find that response for the life of me. Cara or Bob if you remember what I am referring to please HELP!

Thanks,

Marianna

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From: Stephen Daniells [mailto:Stephen.DANIELLS@wrbm.com]
Sent: Wednesday, September 21, 2016 11:33 AM
To: Naum, Marianna
Subject: Dietary Ingredient Database - Natural Products Association

Hi Marianna,

I hope you're doing well. I was wondering if FDA has a comment about this initiative?

Thanks

Stephen

From: Justin Bartolomeo [mailto:jbartolomeo@hdmk.org]
Sent: Wednesday, September 21, 2016 10:11 AM
Subject: Dietary Ingredient Database - Natural Products Association

Natural Products Association

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For Immediate Release
September 21, 2016

Contact: Justin Bartolomeo
(202) 789-4365
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Likewise, FDA's recent NDI guidance stated it was "unlikely to regard a listing in Herbs of Commerce [1992 edition] as being solely determinative of whether a dietary ingredient was marketed as such before October 15, 1994." "The 1992 Herbs of Commerce book includes house plants and herbs not intended for human consumption, so it was not recognized by FDA as an authoritative list of pre-DSHEA dietary ingredients. It also focuses on herbs and does not include the myriad of other dietary ingredients falling within the statutory boundaries of a dietary ingredient created by DSHEA," added Dr. Fabricant.

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Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

# # #

From: Naum, Marianna
To: Tave, Steven; Durkin, Robert; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association
Date: Wednesday, September 21, 2016 1:13:14 PM
Attachments: image001.png

Steve –

I don't think you need to draft anything! We should be able to use the statement we provided for CRN's initiative. I just sent around in another email.

Thanks,
Marianna

Marianna Naum, Ph.D.
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---

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:10 PM
To: Durkin, Robert; Naum, Marianna; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

I will draft something this afternoon. Looks like he already went out with his article anyway.

From: Durkin, Robert
Sent: Wednesday, September 21, 2016 1:09 PM
To: Naum, Marianna; Tave, Steven; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

Not sure how much we could say….it is a topic of the draft guidance and we're in the comment period….

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 12:52 PM
To: Tave, Steven; Durkin, Robert; Welch, Cara
Subject: FW: Dietary Ingredient Database - Natural Products Association

Hey guys,

Please see request below. (b) (5) ? On a side note- I am convinced we addressed this in the past but I cannot find that response for the life of me. Cara or Bob if you remember what I am referring to please HELP!

Thanks,

From: Tave, Steven
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association
Date: Wednesday, September 21, 2016 2:06:54 PM
Attachments: image001.png

Perfect. If you haven't sent it yet, I took out a few words in the 1st sentence to make it slightly less wordy. (And then I added in 2 words in the 2nd-to last sentence to undo that!)

(b) (5)

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 2:02 PM
To: Tave, Steven; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Absolutely not! I say we go out strong.

Marianna Naum, Ph.D.
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---

From: Tave, Steven
Sent: Wednesday, September 21, 2016 2:02 PM
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Yes, as long as it doesn't cause you any concern.

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 2:01 PM
To: Tave, Steven; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Yes I think it makes a lot of sense and I would strongly recommend it! I am assuming you are game?

Marianna Naum, Ph.D.
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---

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:56 PM
To: Naum, Marianna; Welch, Cara; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Thanks. Let's discuss whether it makes sense to quote me directly (it might – curious for your thoughts).

From: Naum, Marianna
Sent: Wednesday, September 21, 2016 1:43 PM
To: Welch, Cara; Tave, Steven; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

I am ok with this –

Thanks,
Marianna

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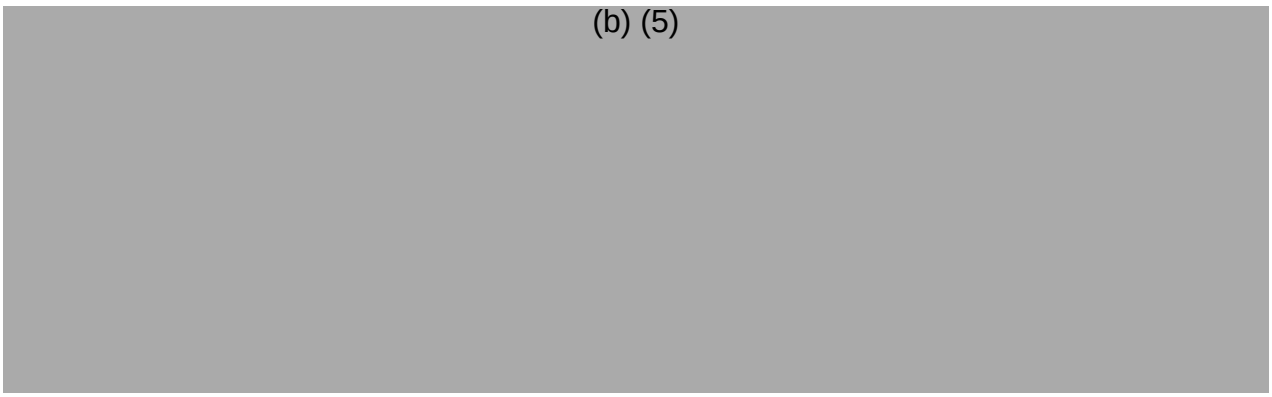
From: Welch, Cara
Sent: Wednesday, September 21, 2016 1:41 PM
To: Tave, Steven; Naum, Marianna; Durkin, Robert
Subject: RE: Dietary Ingredient Database - Natural Products Association

Just one comment to provide added context.

(b) (5)



(b) (5)

From: Tave, Steven
Sent: Wednesday, September 21, 2016 1:30 PM
To: Naum, Marianna; Durkin, Robert; Welch, Cara
Subject: RE: Dietary Ingredient Database - Natural Products Association

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Sent: Wednesday, September 21, 2016 10:11 AM
Subject: Dietary Ingredient Database - Natural Products Association

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Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

# # #

From:	Wheeler, Renee J
To:	Welch, Cara; Benjamin, Dianne; OC-OFVM-ExecSec
Cc:	Swift, Sibyl
Subject:	RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Tuesday, March 17, 2015 11:04:05 AM

Good Morning Cara,

Dianne is on a conference call, I am tracking it down now and will get back to you.

Renee J. Wheeler

From: Welch, Cara
Sent: Tuesday, March 17, 2015 10:18 AM
To: Benjamin, Dianne; OC-OFVM-ExecSec
Cc: Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Dianne et al.,
Can I get an update on the clearance process for this response?
Cara

From: Benjamin, Dianne
Sent: Monday, March 09, 2015 3:52 PM
To: Welch, Cara; OC-OFVM-ExecSec
Cc: Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Thank you Cara.

Dianne

From: Welch, Cara
Sent: Monday, March 09, 2015 12:57 PM
To: Benjamin, Dianne; OC-OFVM-ExecSec
Cc: Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Dianne,
Attached is the original incoming letter from NPA as well as my draft response. This version has been cleared by ORS. Please let me know if you need anything from me on this.
Cara

From: Benjamin, Dianne
Sent: Friday, February 06, 2015 12:31 PM

To: OC-OFVM-ExecSec; Welch, Cara
Cc: Swift, Sibyl; Elkin, Ted
Subject: FW: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Importance: High

All –

See the email trail. This correspondence should be logged into AIMS. Cara's draft must first be Center – cleared and we can discuss who should sign.

Looping in Ted.

Thank you –

Dianne

From: DeLancey, Siobhan
Sent: Friday, February 06, 2015 11:15 AM
To: Barrett, Kari; Benjamin, Dianne
Cc: Shapinsky, David
Subject: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Hi Diane and Kari,

Cara Welch (acting director of the Division of Dietary Supplement Programs) just forwarded this letter she received from the Natural Products Association regarding the announcement Monday by the NY Attorney General's office regarding their testing of dietary supplement products for ingredient verification using DNA sequencing technology.

I wasn't sure who to send this to for tracking and coordination of a response, so am including both of you here.

From: Welch, Cara
Sent: Friday, February 06, 2015 10:43 AM
To: DeLancey, Siobhan
Cc: Harper, Kristina; Elkin, Ted
Subject: FW: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Siobhan, this is the letter I rec'd from NPA re: the NY AG topic. I realize this isn't as timely as the press inquiries with 2 hour deadlines but eventually we'll have to respond.

Tina, just wanted to keep you in the loop as well. Let me know if you want to discuss this.

Cara

From:	Benjamin, Dianne
To:	Welch, Cara; OC-OFVM-ExecSec
Cc:	Swift, Sibyl
Subject:	RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Monday, March 09, 2015 3:52:19 PM

Thank you Cara.

Dianne

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Cara

Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Thursday, February 05, 2015 5:53 PM
To: Welch, Cara
Cc: Harper, Kristina
Subject: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Lauren Cohen
Vice President, Public Relations & Communications
Natural Products Association
Washington, DC

February 5, 2015

Cara Welch
Acting Director
Division of Dietary Supplement Programs
Food and Drug Administration
College Park, MD

Dear Dr. Welch,

On Tuesday, February 3, New York State Attorney General Eric Schneiderman ordered four major retailers to stop selling store-brand herbal supplements. All four retailers have received cease-and-desist letters demanding that they halt the sales of these supplements because a third-party testing lab used DNA barcoding to identify botanical ingredients, listed on the label, through a type of "genetic fingerprinting", and discovered evidence to the contrary. A total of 19 out of the 24 products tested supposedly contained DNA that was either unrecognizable or from a plant other than what was claimed on the label.

The Natural Products Association and the dietary supplement industry as a whole are concerned about this issue on several levels. There is no question that DNA finger printing is a powerful tool for natural product authentication, including raw materials before extraction. The information provided by the New York Attorney General fails to mention the listing of botanical extracts as dietary ingredients in these herbal supplement products. Botanical extracts involve the use of alcohol or other solvent to extract the final dietary ingredient from the source botanical. The use of DNA barcoding methodology on extracts of raw ingredients is neither a good, better, or best standard of practice in the dietary supplement industry.

We ask the Food and Drug Administration to opine on whether this DNA barcoding technology is appropriate, sensitive, specific and scientifically valid for routine use by the dietary supplement industry to definitely identify botanicals used as the starting source material to create botanical extracts. If it is not commonly used for extracts of raw botanicals in finished products to identify botanical sources, why is this methodology being given credibility at this time. The concern is that DNA will be sufficiently degraded during the extraction and manufacturing process that intact DNA markers specific to a particular botanical will not be detected. Therefore, is the technology fit for purpose in botanical identity with regard to routine use in dietary supplements containing botanical extracts?

Thank you for your attention to this important matter, and we hope the FDA can shed light on the scientific validity of this study.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org


From:	Benjamin, Dianne
To:	Welch, Cara
Cc:	Swift, Sibyl
Subject:	RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Friday, February 06, 2015 3:00:01 PM
Attachments:	NY AG Key Messages 020515 v3.doc

Cara –

Did you have a copy of our talking points? If not, here they are.

Dianne

From: Welch, Cara
Sent: Friday, February 06, 2015 12:33 PM
To: Benjamin, Dianne; OC-OFVM-ExecSec
Cc: Swift, Sibyl; Elkin, Ted
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

The attachment states the same as the email but wanted to be sure it was shared as well
Cara

From: Benjamin, Dianne
Sent: Friday, February 06, 2015 12:31 PM
To: OC-OFVM-ExecSec; Welch, Cara
Cc: Swift, Sibyl; Elkin, Ted
Subject: FW: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Importance: High

All –

See the email trail. This correspondence should be logged into AIMS. Cara's draft must first be Center – cleared and we can discuss who should sign.

Looping in Ted.

Thank you –

Dianne

From: DeLancey, Siobhan
Sent: Friday, February 06, 2015 11:15 AM
To: Barrett, Kari; Benjamin, Dianne
Cc: Shapinsky, David
Subject: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Hi Diane and Kari,

Cara Welch (acting director of the Division of Dietary Supplement Programs) just forwarded this letter she received from the Natural Products Association regarding the announcement Monday by the NY Attorney General's office regarding their testing of dietary supplement products for ingredient verification using DNA sequencing technology.

I wasn't sure who to send this to for tracking and coordination of a response, so am including both of you here.

From: Welch, Cara
Sent: Friday, February 06, 2015 10:43 AM
To: DeLancey, Siobhan
Cc: Harper, Kristina; Elkin, Ted
Subject: FW: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Siobhan, this is the letter I rec'd from NPA re: the NY AG topic. I realize this isn't as timely as the press inquiries with 2 hour deadlines but eventually we'll have to respond.

Tina, just wanted to keep you in the loop as well. Let me know if you want to discuss this.

Cara

Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Thursday, February 05, 2015 5:53 PM
To: Welch, Cara
Cc: Harper, Kristina
Subject: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Lauren Cohen
Vice President, Public Relations & Communications
Natural Products Association
Washington, DC

February 5, 2015

Cara Welch
Acting Director
Division of Dietary Supplement Programs
Food and Drug Administration
College Park, MD

Dear Dr. Welch,

On Tuesday, February 3, New York State Attorney General Eric Schneiderman ordered four major retailers to stop selling store-brand herbal supplements. All four retailers have received cease-and-desist letters demanding that they halt the sales of these supplements because a third-party testing lab used DNA barcoding to identify botanical ingredients, listed on the label, through a type of "genetic fingerprinting", and discovered evidence to the contrary. A total of 19 out of the 24 products tested supposedly contained DNA that was either unrecognizable or from a plant other than what was claimed on the label.

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Thank you for your attention to this important matter, and we hope the FDA can shed light on the scientific validity of this study.

Sincerely,

From:	Wheeler, Renee J
To:	Welch, Cara
Subject:	RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Tuesday, March 17, 2015 11:15:38 AM

Okay, I think we should be good then.

Renee

From: Welch, Cara
Sent: Tuesday, March 17, 2015 11:15 AM
To: Wheeler, Renee J
Cc: OC-OFVM-ExecSec; Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

The incoming letter was sent to me so I assumed I would be signing the response. I don't think it needs OCC clearance – this response is (b) (5) .

Cara

From: Wheeler, Renee J
Sent: Tuesday, March 17, 2015 11:09 AM
To: Welch, Cara
Cc: OC-OFVM-ExecSec
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

I have it Cara and will send to Foods shortly for clearance. Who's signing the letter and do think it needs OCC clearance, Ted has cleared it for CFSAN.

Renee

From: Welch, Cara
Sent: Tuesday, March 17, 2015 10:18 AM
To: Benjamin, Dianne; OC-OFVM-ExecSec
Cc: Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Dianne et al.,

Can I get an update on the clearance process for this response?

Cara

From: Benjamin, Dianne
Sent: Monday, March 09, 2015 3:52 PM
To: Welch, Cara; OC-OFVM-ExecSec
Cc: Swift, Sibyl

Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Thank you Cara.

Dianne

From: Welch, Cara
Sent: Monday, March 09, 2015 12:57 PM
To: Benjamin, Dianne; OC-OFVM-ExecSec
Cc: Swift, Sibyl
Subject: RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Dianne,
Attached is the original incoming letter from NPA as well as my draft response. This version has been cleared by ORS. Please let me know if you need anything from me on this.
Cara

From: Benjamin, Dianne
Sent: Friday, February 06, 2015 12:31 PM
To: OC-OFVM-ExecSec; Welch, Cara
Cc: Swift, Sibyl; Elkin, Ted
Subject: FW: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Importance: High

All –

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Sent: Thursday, February 05, 2015 5:53 PM
To: Welch, Cara
Cc: Harper, Kristina
Subject: Regarding scientific validity of DNA methods for botanical ingredients after extraction

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Vice President, Public Relations & Communications
Natural Products Association
Washington, DC

February 5, 2015

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Food and Drug Administration
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VP, Public Relations & Communications
Natural Products Association

1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org


From: Tave, Steven
To: Welch, Cara
Subject: RE: Natural Products Association Applauds Launch of Supplement OWL—Urges NPA members to explore how to get their dietary supplement labels in the online registry
Date: Thursday, April 20, 2017 11:21:26 AM

So – while (b) (5) ?
Wow.

From: Welch, Cara
Sent: Thursday, April 20, 2017 11:19 AM
To: Tave, Steven
Subject: FW: Natural Products Association Applauds Launch of Supplement OWL—Urges NPA members to explore how to get their dietary supplement labels in the online registry

"said NPA Executive Director & CEO Daniel Fabricant, Ph.D. "This is a project that NPA Chairman Mark LeDoux and I have been discussing since I was still at the FDA…"

It's impressive that he can still work this into his public quotes ☺

From: Vogtman, Holly [mailto:hvogtman@crnusa.org]
Sent: Thursday, April 20, 2017 10:18 AM
To: Welch, Cara
Subject: Natural Products Association Applauds Launch of Supplement OWL—Urges NPA members to explore how to get their dietary supplement labels in the online registry

For Immediate Release

Contacts:

CRN Holly Vogtman, 202-204-7665

NPA Justin Bartolomeo, 202-789-4365

Natural Products Association Applauds Launch of Supplement OWL
—Urges NPA members to explore how to get their dietary supplement labels in the online registry—

Washington, D.C., *April 20, 2017*—The Natural Products Association (NPA) today offered its enthusiastic support for the Supplement OWL, the new online dietary supplement registry launching in April. In making the announcement, NPA encouraged its members to learn more about how to enter their dietary supplements in the Supplement OWL and to add their product labels to the growing collection of products represented in this online library of the dietary supplement industry.

“This is another example of the industry working together to give consumers what they deserve: confidence to know the products they take each and every day are safe and beneficial. As part of our commitment to supporting the suppliers, manufacturers, consumers and regulators of the natural products industry, NPA offers our full support for this new and exciting initiative,” said NPA Executive Director & CEO Daniel Fabricant, Ph.D. “This is a project that NPA Chairman Mark LeDoux and I have been discussing since I was still at the FDA. We are already receiving positive feedback from early participants in the program, and we urge the rest of our members to get on board. The success of this initiative depends on strong participation from all corners of the natural products market and we expect the program to be a tremendous benefit to everyone involved.”

“The Supplement OWL is the result of a great deal of bold initiative, forethought and creative thinking by many in the industry. We appreciate that leaders at NPA and its members, like GNC, were involved early in the brainstorming process of what an industry-run registry might entail. Working with our partner, UL, and many others in the industry, these leaders helped craft the early framework for the Supplement OWL,” said Steve Mister, President & CEO of the Council for Responsible Nutrition (CRN). “We are delighted that NPA is urging its membership to participate in this effort.”

The Supplement OWL will be live later in April with the release of the public interface of the registry (www.SupplementOWL.org). The Supplement OWLallows users to access the registry through the internet and to search product entries by brand name, ingredient, health category and a host of other options. The registry provides ingredient listings, serving sizes, a copy of the *Supplement Facts* box, and other information about the supplements. Participation in the registry is free and open to all marketers of legitimate dietary supplements sold in the United States.

“NPA was one of the early pioneers in assembling its members’ labels through its TruLabel Program going back to the 1990s,” Mister acknowledged. “Even before the online access and search capabilities offered by today’s technology, the TruLabel program captured basic product details for NPA’s members. Today, the Supplement OWL offers sort and search abilities and full online access for retailers and consumers to complete images of product labels.”

“NPA will soon be announcing details of its new TruLabel testing program,” Fabricant offered. “This component of TruLabel will strengthen the program and provide even more details and resources to increase the accuracy of product labeling and ingredient authenticity. As the Supplement OWL expands, we are hopeful that these test results can also be made part of the registry and help to inform retailers and consumers about products in the marketplace.”

Mister agreed. “In addition to the basic label information stored in the Supplement OWL registry, additional fields of information in Tier 2 of the Supplement OWL will

allow retailers to verify product labels with background materials and documentation uploaded to the registry.

Testing results from programs like TruLabel will be ideal for helping retailers decide which supplements they want in their stores," Mister explained.

A free webinar, "Getting Started with the Supplement OWL Dietary Supplement Product Registry," will be held on Wednesday, April 25 at 2 pm EDT to help companies learn more about getting their product labels into the Supplement OWL. More information about the webinar is available here.

Natural Products Association (NPA) is the trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. NPA has set numerous industry standards, such as dietary supplement Good Manufacturing Practices (GMPs), as well as a definition of natural for home care and personal care products. NPA, which represents over 2,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids, has led the charge to keep the natural products industry in business for 79 years. Visit www.NPAinfo.org.

The **Council for Responsible Nutrition (CRN)** , founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @crn_supplements and @wannabewell and on Facebook.

This email was sent by:
Council for Responsible Nutrition
1828 L Street, NW, Suite 510 Washington, DC, 20036-5114, US

From: Welch, Cara
To: Tave, Steven; Durkin, Robert (Robert.Durkin@fda.hhs.gov)
Subject: FW: NPA Thursday Roundup
Date: Friday, December 22, 2017 1:21:00 PM

But seriously, the excitement in this email is almost palpable. LOL

"first again, first ever" (2nd story down) and then "First Event Partner to the Second Iteration of The Big Natural" (~6th story down?).

From: Joel and Cara Welch
Sent: Friday, December 22, 2017 11:18 AM
To: Welch, Cara <Cara.Welch@fda.hhs.gov>
Subject: Fwd: NPA Thursday Roundup

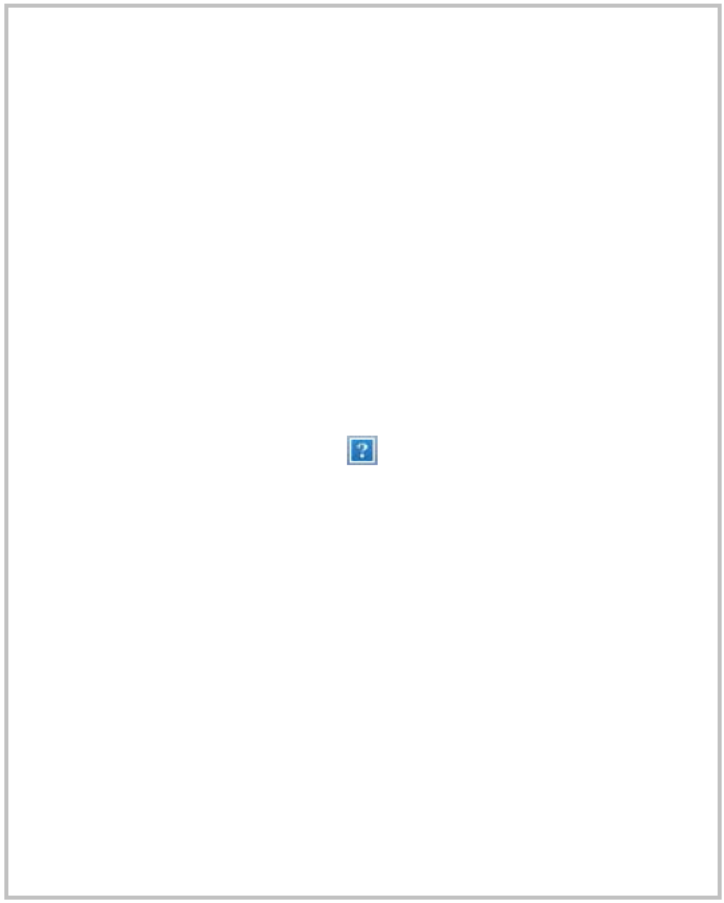
---------- Forwarded message ----------
From: **Dr. Daniel Fabricant** <daniel.fabricant@npanational.org>
Date: Thu, Dec 21, 2017 at 3:59 PM
Subject: NPA Thursday Roundup
To: (b) (6)

View web version

December 21, 2017

NPA Meets with OMB to Discuss the Nutrition and Supplement Facts Labeling Final Rule

Last week, Dr. Fabricant met with OMB to discuss the nutrition and supplement facts labeling final rule. A very important matter given that the industry has to spend $200 million to made label changes. The unduly, burdensome changes seen in the final rule now require dietary fibers firms to do 2 RCTs (Random Clinical Trials) to show a beneficial physiological effect. In addition, the eye tracking studies, designed to support some of the new changes like added sugars, do not support FDA's position in this final rule. Furthermore, the FDA failed to submit an economic impact analysis with the guidance to OMB regarding this new cost burden to the food and supplement industry. If the Agency is implementing such burdensome changes, they must first provide material evidence in the form of substantiated consumer studies, which serves as the basis for the labeling changes. Therefore, NPA is requesting a 3 year extension in the compliance date for the final rule, as it provides sufficient time for the agency to conduct proper empirical studies involving consumer research and will allow for accurate and consistent changes to be made, without crippling costs to business that will be passed on to all American consumers.



NPA and Their Members Are First Again, First Ever Request of Its Kind (Using the IFR on Reduced ID Testing) Submitted on Behalf of Bergstrom Nutrition

A request made on behalf of Bergstrom Nutrition by the Natural Products Association (NPA) to the Food and Drug Administration (FDA) could lead to lower costs for consumers and the federal government and increase the overall quality of nutritional supplements. This is the first time a manufacturer has submitted a Citizen Petition requesting a reduction in identity testing while showing no diminution in product quality, based upon their historical record of demonstrating high quality.

Click here for the news release and the Citizen Petition.

NPA Makes a Statement on NBC's Nightly News Regarding FDA's Draft Guidance on “Drug Products Labeled as Homeopathic”

FDA says it will crack down on homeopathic products. NPA responds.

Click here to watch the video.

Dan Fabricant on Leadership in Action

Dan Fabricant was interviewed on Business Radio's *Leadership in Action* on Sirius XM.

Click here to listen to the interview.

Register for Natural Products Day 2018

Each year, the natural products industry gathers in our nation’s capital to educate members of Congress and legislative staff about the important role natural products play in keeping Americans healthy and the overwhelming public benefits of preventive care. This day-long advocacy conference is hosted each year by NPA to provide retailers, suppliers, and all industry stakeholders from across the country with the opportunity to become lobbyists for a day.

There is no registration cost to attend and all meetings will be arranged by NPA.

For questions and registration, email Natural@NPAnational.org

From:	Welch, Cara
To:	Strambler, Karen
Cc:	Zajac, Andrew J; Assar, Carrie
Subject:	FW: Meeting Request with NPA re: Carrageenan Advisory Committee
Date:	Thursday, May 19, 2016 8:49:00 AM
Attachments:	image013.png image014.png image003.png image004.png

Karen,
OFAS, ONFL, and ODSP were contacted by the Natural Products Association for a meeting request re: Carrageenan. At this point, I'm (b) (5) since I'm not aware of dietary supplement concerns with carrageenan. Since you're the food advisory committee federal officer, I wanted to get your opinion on the request.
Thanks
Cara

From: Michael Kelley [mailto:mkelley@npainfo.org]
Sent: Thursday, May 12, 2016 12:07 PM
To: Assar, Carrie; Mattia, Antonia; Welch, Cara; Mozersky, Robert
Cc: Daniel Fabricant, Ph.D.; Corey Hilmas
Subject: Meeting Request with NPA re: Carrageenan Advisory Committee

Good Afternoon-

Mike Kelley with the NPA here. I hope this email finds you all well.

NPA would like to request a meeting to discuss adding Carrageenan to the list of current FDA Advisory Committees. Could you let me know if there a specific date and time that works for your team in the coming weeks?

Thank you in advance,

Mike

Michael Kelley
Director, Government Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office: (202) 204-4720
Cell: (703) 509-7052
www.NPAinfo.org

From: Welch, Cara
To: Tave, Steven; Durkin, Robert (Robert.Durkin@fda.hhs.gov)
Subject: FW: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source
Date: Thursday, January 12, 2017 11:51:00 AM

http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/NPA%20Letter%20to%20President-Elect%20Trump.pdf

From: NutraIngredients-USA [mailto:newsletter@nutraingredients-usa.com]
Sent: Thursday, January 12, 2017 11:23 AM
To: Welch, Cara
Subject: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

TODAY'S HEADLINES

NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods onboard

The Natural Products Association has officially launched the Supplement Safety and Compliance Initiative (SSCI), with some of the largest retailers of natural products and supplements involved... Read

FTC outlines lessons for MLMs following Herbalife and Vemma cases

The Federal Trade Commission has released guidance for MLMs based on lessons learned

from the FTC's cases against Herbalife and Vemma... Read

NPA outlines top supplement-related legislative issues for PEOTUS Trump

NDIs, kratom, maternal and child nutrition, medical foods, health claims, and reducing the cost of healthcare are among the important issues affecting dietary supplements and the natural products industry in 2017, according to the Natural Products Association. .. Read

Sabinsa study supports DigeZyme's benefit in relieving post-exercise soreness

Sabinsa's researchers in Bangalore, India, found that the branded multi-enzyme complex ingredient DigeZyme improved the outcome measures related to delayed onset muscle soreness after exercise, compared to placebo... Read

Heard of the gut-brain axis? Meet the gut-skin axis...

Probiotic supplementation may improve adult acne appearance as researchers discuss the existence of a gut-skin axis in which the gastrointestinal area is targeted by bacterial strains to affect skin physiology... Read

Aquatic plant potential: Why duckweed could become a source of protein and omega-3 beyond South East Asia

Duckweed has long been consumed as an inexpensive protein and source of omega-3 in several South East Asia countries, but now researchers are questioning if it has the potential to be adopted by south Asian and even Western consumers too... Read

All News Headlines for: January December November

EDITOR'S CHOICE

Marketers of Prevagen charged with making false and unsubstantiated claims by FTC, NY AG

Quincy Bioscience, marketers of brain health product Prevagen, has been charged with making deceptive memory, cognitive improvement claims by the Federal Trade Commission and New York State Attorney General... Read

Raising the bar: CRN and IPA release best practice guidelines for probiotics

New best practices guidelines for the labeling, storing, and stability testing for probiotic products will facilitate transparency and consistency in the US probiotics sector... Read

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Reducing sodium intake could save more lives, money than treating related disease, study finds

Ambitious sodium reduction targets for the next two and 10 years laid out by FDA in draft voluntary guidance released last summer not only could save lives, but they could generate huge cost savings based on new research published this week in The BMJ. .. Read

KitoZyme banking on novel prebiotic with new medical device platform

Belgian firm KitoZyme is planning a roll out of of medical device products that put restoring gut flora at centre stage, company told Nutraingredients after receiving two new certifications... Read

DATELINE SOUTHEAST ASIA

Indonesia hints at halal mark, urges firms to target Islamic market

Plus: Hanoi ramps up local agri-inspections due to lack of safe local food; and El Niño disruption causes palm kernel prices to double... Read

Chicory extract found to improve memory loss in mice: China study

Chicoric acid (CA), a nutraceutical component from the chicory plant could slow down memory loss associated with Alzheimer's and other neurodegenerative diseases, a study revealed... Read

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- **What Is the Most Bioavailable, Organic Form of Magnesium?** - Albion
- **Bioavailable and Stable Ubiquinol CoQH-CF Softgels** - Soft Gel
- **Aronox® – powerful, natural heart health benefits** - Naturex
- **Pioneering probiotics application in the Brain-Gut axis** - Lallemand Health Solutions: your probiotic solutions provider
- **US CONSUMERS INTERESTED IN FIBER TO IMPROVE HEALTH** - Sensus
- **Patented Lychee Extract for Sports Nutrition and RTD Applications** - Maypro Industries
- **UC-II® Joint Health Gummies** - InterHealth Nutraceuticals, Inc.
- **Strategic Nutrition for Eye Health** - Fortitech Premixes, by DSM
- **élantria™ - A New Standard In Stability for Omega-3** - PLT Health Solutions
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Le Belem - 355, rue Vendemiaire - 34000 Montpellier - France
https://www.william-reed.com

From: Welch, Cara
To: Swift, Sibyl
Subject: Re: AHPA NPA Joint Letter
Date: Friday, September 11, 2015 7:51:16 AM

Totally…thanks!

From: Swift, Sibyl
Sent: Friday, September 11, 2015 07:40 AM
To: Welch, Cara
Subject: RE: AHPA NPA Joint Letter

I hadn't heard anything on this one. I'm just sending this email as a friendly reminder that you were going to draft a response. If you don't mind, let me know when it goes out so that I can close it out in AIMS.

Thank you!!

From: Welch, Cara
Sent: Monday, August 31, 2015 4:21 PM
To: Swift, Sibyl
Cc: Durkin, Robert; Robinson, Latasha A
Subject: FW: AHPA NPA Joint Letter

Sibyl,
Will you log this into our system for correspondence? We're still doing some research on the appropriate answer…to ensure we're consistent with how we've previously treated this type of situation.
Thanks
Cara

From: Corey Hilmas [mailto:corey.hilmas@npainfo.org]
Sent: Monday, August 31, 2015 1:39 PM
To: Welch, Cara; Robinson, Latasha A
Cc: 'Michael McGuffin'; Daniel Fabricant, Ph.D.
Subject: AHPA NPA Joint Letter

Dear Dr. Welch and Ms. Robinson,

The American Herbal Products Association (AHPA) and the Natural Products Association (NPA) have drafted a joint letter requesting clarification on the labeling of an herbal dietary ingredient for use in dietary supplements, pursuant to 21 CFR 101.4(h). We hope that you would be able to shed light and provide direction on this issue for us.

Sincerely,

Corey J. Hilmas, M.D., Ph.D.
Senior Vice President of Scientific & Regulatory Affairs
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Office 202.223.0101 x109
Direct 202.204.4725
Cell 443.632.8365
Fax 202.223.0250
www.NPAinfo.org

From:	Welch, Cara
To:	DeLancey, Siobhan; Levy, Dan D.
Subject:	RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements
Date:	Wednesday, November 05, 2014 8:43:00 AM
Attachments:	DS interaction response v2.1cw.doc

Attached are a few edits from me
Cara

From: DeLancey, Siobhan
Sent: Wednesday, November 05, 2014 6:28 AM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: RE: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Just putting this front of mind for follow-up this morning. I received comments from Charlotte last night and they are incorporated in the attachment.

One thing that we discussed last night was the language regarding (b) (5) Whether or not this particular point winds up in the response to NPA, I do expect the Tan Sheet reporter will ask about, so it would be better to noodle it out ahead of time.

I'll be at CFSAN today and can stop by for in-person discussion if needed. Thanks!

From: DeLancey, Siobhan
Sent: Tuesday, November 04, 2014 4:02 PM
To: Poos, Mary; Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC; Welch, Cara; Levy, Dan D.
Cc: Shapinsky, David; Schor, Danielle
Subject: For review: Response to NPA Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Hi all,

I've been tasked with drafting a response to the letter writer. NPA has also shared the letter with the Tan Sheet, which is requesting a response as well. I have informed the reporter that we plan to respond directly to NPA first. Please take a look at what I've drafted below and see if it accurately characterizes our position. I've also attached the original letter, and you can reference the CU itself at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm420349.htm.

Once you have provided your comments, I will send a revised version for CFSAN OCD clearance and then to OEA.

(b) (5)

From: Poos, Mary
Sent: Monday, November 03, 2014 1:52 PM
To: Spiller, Philip C; Mozersky, Robert; Christin, Charlotte - OC
Cc: Shapinsky, David; Welch, Cara; Levy, Dan D.; Schor, Danielle
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

We did not develop it, CDER did, but I and others reviewed and cleared it. I think NPA's letter is (b) (5) . There is nothing for us to do (b) (5) with respect to what it says.

From: Spiller, Philip C
Sent: Monday, November 03, 2014 1:08 PM
To: Mozersky, Robert; Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle
Cc: Shapinsky, David; Poos, Mary; Welch, Cara
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Idle curiosity question for today: Did DDSP participate in developing this consumer update?

From: Mozersky, Robert
Sent: Monday, November 03, 2014 12:52 PM
To: Christin, Charlotte - OC; Levy, Dan D.; Schor, Danielle
Cc: Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

The article does not mention that dietary supplements should have labels.
Its point is that consumer's should know what they are taking by asking a health care provider.

Robert Mozersky, D.O.
Medical Officer
Division of Dietary Supplement Products
HFS-810
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Phone: 240-402-1445
FAX #: 301-436-2636

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 12:33 PM
To: Levy, Dan D.; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C; Welch, Cara
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks. Will circle back later.

From: Levy, Dan D.
Sent: Monday, November 03, 2014 12:32 PM
To: Christin, Charlotte - OC; Schor, Danielle
Cc: Mozersky, Robert; Shapinsky, David; Poos, Mary; Spiller, Philip C
Subject: Re: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

This looks more like a litigation brief than a friendly note from their communications director.

I think the only response, if any, is that we review each labeling situation on a case by case basis and we always value input from NPA and other stakeholders on how to do that.

From: Christin, Charlotte - OC
Sent: Monday, November 03, 2014 11:53 AM

To: Schor, Danielle
Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: RE: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Thanks, Dani. I'm tied up in meetings until later this afternoon and will look at this then.

From: Schor, Danielle
Sent: Monday, November 03, 2014 11:49 AM
To: Christin, Charlotte - OC
Cc: Levy, Dan D.; Mozersky, Robert; Shapinsky, David
Subject: FW: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Charlotte

I know you are no longer involved with dietary supplements, but this consumer update was prepared some time ago and I wanted to include you as well as Dan and Robert, since he is quoted.

We received this comment below from the Natural Products Assoc. on the consumer update, which is linked in NPA's email. We don't necessarily think there is anything wrong with the Consumer Update and NPA may be providing an opinion that we don't share. I just wanted to get everyone's take on how we should respond.

Many thanks.

Dani Schor, R.D.¦ Communications and Public Engagement Staff
FDA Office of Foods and Veterinary Medicine
301.796.5404 (phone) ¦240.205.2886 (cell)
danielle.schor@fda.hhs.gov ¦ WO Bldg 1, room 3240

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Friday, October 31, 2014 03:53 PM
To: Immergut, Steven
Cc: Taylor, Michael R; Natanblut, Sharon
Subject: Regarding FDA Consumer Update, Mixing Medications and Dietary Supplements

Dear Mr. Immergut,

As the leading trade association representing the dietary supplement industry, the Natural Products Association (NPA) is requesting a few clarifications be made to the Food and Drug Administration's (FDA) recent consumer update, Mixing Medications and Dietary Supplements Can Endanger Your Health. We are disappointed to see this type of communication from the agency, as it seems sensational in nature, and provides misleading information related to dietary supplements as compared to other foods.

As you more than likely are aware, the FDA has never pursued the requirement of a label warning for dietary supplements regarding their interaction with pharmaceuticals. The FDA has never found it to be material fact to change consumer behavior consistent with the Central Hudson test[1] for

labeling. Your consumer update suggests that some dietary supplements need a warning statement, when compelling such a warning label on dietary supplement products would require convincing evidence rather than mere speculation or furthering a stated interest by informing consumers. The Supreme Court's use of the Central Hudson test should be the standard by which food law regulations are analyzed, whether bans, required disclosures or warnings. In applying the Central Hudson test, the Second Circuit Court concluded that the regulating agency did not claim that health or safety concerns prompted the passage of a certain labeling law, but instead found its interest relied on informing the consumer. Therefore, the agency interest "in the public right to know" was "insufficient to justify compromising protected constitutional rights" under the First Amendment.[2]

It is the agency's burden to demonstrate the harms it recites are real and that its restriction will, in fact, alleviate them to a material degree. Therefore, absent material fact with evidence or empirical data, NPA believes it is misleading for the agency to draw the conclusion in a statement to consumers that dietary supplements are putting them at risk more than other categories of food. NPA has supported the FDA's mission on protecting the public health, including adequate funding for the agency, and adding statutory authority (i.e., serious adverse event reporting requirement); however, it is unclear as to why the FDA positioned its communication that dietary supplements pose more risk or harm than other foods when used with pharmaceuticals. If the FDA seeks to make such a statement, it must have compelling evidence. The comments in the consumer advisory were irresponsible in the absence of material fact to compel a label warning on dietary supplements.

Furthermore, there already exists required warning statements on medications to warn consumers regarding potentially dangerous combinations with that particular drug product. The consumer update reads, "Some consumers may believe that a so-called 'natural' product, such as an herbal supplement or fish oil, can't hurt them. ... For example, many weight loss products claim to be 'all-natural' or 'herbal,' but their ingredients may interact with medications or may be dangerous for people with certain medical conditions." This indicates that the supplement is posing a risk, when, in fact, the particular drug product is already required to be properly labeled with appropriate warning statements regarding side effects. The messaging here creates confusion, as now consumers may falsely believe that the supplements they are taking each day should contain warning statements or that the products are misbranded because they fail to declare a particular warning statement. We recommend editing your consumer piece to reflect this point. Moreover, if the agency is concerned with a specific dietary ingredient found in supplement form, why isn't it making similar warnings on the whole food version? For example, the consumer update specifically references fish oil, but yet the agency hasn't made the same statement regarding fatty fish, such as salmon, that are high in omega-3 fatty acids.

Finally, NPA takes issue with the section, "What is FDA's Role." The dietary supplement industry has many robust agency regulations in place. Dietary supplements are regulated as a food product under the Dietary Supplement Health and Education Act, and consistently meet the government and industry standards that have been set. In fact, dietary supplements are the only category of food where submission of serious adverse event reports are a mandatory requirement. The same reporting requirement is not required of other foods, such as grapefruits, that are known to interact with various medications. Additionally, dietary supplement labels must carry contact information for consumers to report serious adverse events. No other categories of food are required to do this. The

agency must ensure it is even-handed and science-based toward public health concerns to keep consumers safe.

NPA supports the position that consumers should consult their physician any time they are supplementing their diet, making a change in their diet, or seeking advice on a medication. A more important focus for this consumer update would have been to emphasize the importance of talking with a doctor before starting any medication or dietary supplement or making any changes to one's health care regimen.

NPA asks that you please clarify the inaccuracies in this piece so that consumers can be better educated on the topic at hand.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
1773 T Street, NW
Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
www.NPAinfo.org


[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).
[1] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

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[1] Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York, 447 U.S. 557, 563 (1980).

[2] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2d Cir. 1996), Id. At 73.

From:	Welch, Cara
To:	Clapp, Nicole; Pillsbury, Laura
Cc:	Durkin, Robert; Barrett, Kari; Natanblut, Sharon; Cruz, Marisa; Elkin, Ted
Subject:	RE: Meeting with CRN, AHPA, NPA, UNPA and CHPA
Date:	Wednesday, August 26, 2015 10:11:00 AM

Yes, we'll work with Exec Sec to coordinate with the associations

From: Clapp, Nicole
Sent: Wednesday, August 26, 2015 10:10 AM
To: Welch, Cara; Pillsbury, Laura
Cc: Durkin, Robert; Barrett, Kari; Natanblut, Sharon; Cruz, Marisa; Elkin, Ted
Subject: Meeting with CRN, AHPA, NPA, UNPA and CHPA

Hi Cara – No, I'm all set and sorry for the delay. I'll reach out to group from the last meeting to gauge availability the week of September 28th. I'll return to you with options.

I believe I may have touched on this previously however, once the date has been nailed down, will you loop in Exec Sec to coordinate the agenda/materials?

Thank you, Nicole

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Welch, Cara
Sent: Wednesday, August 26, 2015 10:07 AM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Durkin, Robert
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Nicole,
I wanted to touch base on this request – please let me know if you need anything from us.
Thanks
Cara

From: Welch, Cara
Sent: Thursday, August 20, 2015 12:41 PM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Thanks Nicole. Yes, we'd be expecting the same SMEs as the meeting yesterday with CRN.
Cara

From: Clapp, Nicole
Sent: Thursday, August 20, 2015 12:38 PM
To: Welch, Cara; Pillsbury, Laura

Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Hi Cara – Mike's in Milan for most of the week of the 21st. I'll look at the week of the 28th. I'll need to consider the availability of the SMEs as well... same folks as from the meeting with CRN

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Welch, Cara
Sent: Wednesday, August 19, 2015 3:45 PM
To: Clapp, Nicole; Pillsbury, Laura
Cc: Cruz, Marisa; Durkin, Robert; Elkin, Ted; Natanblut, Sharon; Barrett, Kari
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Nicole,
During our meeting with CRN today, Mike suggested we get a time scheduled for a meeting between OFVM/CFSAN and the 5 trade associations mentioned at the bottom of this email chain. CRN suggested we look at the week of Sept 21 or Sept 28 – could you provide some days/times for an hour long meeting with this group?
Thanks
Cara

Cara Welch, Ph.D.
Acting Deputy Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Pillsbury, Laura
Sent: Wednesday, July 22, 2015 7:15 PM
To: Welch, Cara; Durkin, Robert; Elkin, Ted
Cc: Cruz, Marisa; Clapp, Nicole
Subject: FW: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

As requested -

From: Clapp, Nicole
Sent: Thursday, July 16, 2015 4:00 PM
To: Steve Mister
Cc: Pillsbury, Laura; Clapp, Nicole
Subject: RE: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Thanks, Steve – we'll review your request with Mike and get back to you as soon as possible.

Best, Nicole

Nicole M. Clapp
Executive Assistant to the Deputy Commissioner for Foods and Veterinary Medicine
FDA/Office of Foods and Veterinary Medicine (OFVM) ¦ White Oak Bldg 1-Room 3241
301-796-4665 ¦nicole.clapp@fda.hhs.gov

From: Steve Mister [mailto:SMister@crnusa.org]
Sent: Thursday, July 16, 2015 3:48 PM
To: Taylor, Michael R; Clapp, Nicole
Subject: Meeting Request: on behalf of CRN, AHPA, NPA, UNPA and CHPA

Mike – On behalf of my own organization, CRN, along with the American Herbal Products Association (AHPA), the Natural Products Association (NPA), the United Natural Products Alliance (UNPA) and the Consumer Healthcare Products Association (CHPA), I am contacting you to request a meeting. The five associations collectively represent all aspects of the dietary supplement industry. We would like to meet with you to discuss:

- Ongoing speculation that CFSAN may be considering elevating the Division of Dietary Supplement Programs to an Office level within the agency. The five industry organizations are supportive of this move and would like to learn more about this possibility and what we assistance might be able to provide (e.g., letters to members of Congress, letter of support to HHS, etc.) to make this a reality.
- The matter of a joint industry-FDA symposium examining dietary supplements. Mike, we have discussed this matter with you on a couple of occasions as well as numerous people throughout CFSAN over the past three years – Dr. Fabricant (when he was still at FDA), Dr. Welch, Mr. Spiller, Mr. Elkin. It was one of the topics you discussed with CRN in February of this year when we met with your office. For the past four years, the industry has been told repeatedly that there is no objection to this concept from FDA – in fact, the OTC industry has successfully conducted a similar program with CDER for the past ten years. We have sent multiple copies of a proposed agreement to FDA for your review and signature. Likewise, we have been told the agreement has received approval from FDA's ethics office and there is no internal objection to it. Yet we cannot get FDA to sign the agreement. We would like to discuss this matter and what can be done to move this initiative forward. (Most recently, the agreement was attached to my email to you dated June 17, 2015.)

Given vacation schedules, it may be difficult to schedule this meeting before mid-August, however, we will try to accommodate your own schedule and would invite you to provide us with a few dates that you might be available after August 10th. We anticipate the meeting would take about 30 minutes.

We will look forward to meeting with you and look forward to your response.

Steve Mister
President & CEO
Council for Responsible Nutrition
1828 L Street, NW, Suite 510
Washington, D.C. 20036
(202) 204-7676

From: Welch, Cara
To: Tave, Steven
Subject: RE: NPA and caffeine
Date: Monday, November 07, 2016 4:14:00 PM

In the press, yes. I'm not aware there is an association position on it.

http://www.npr.org/sections/health-shots/2014/12/31/371692640/potent-powdered-caffeine-raises-safety-worries

But Daniel Fabricant, executive director of the Natural Products Association, says the problem is not with the product, but with people misusing it.

"It is the dosage that makes anything a poison," Fabricant says. "Take water for example, [or] salt for example — if you use too much, it creates problems. I think that's really the issue here. People safely use caffeine every day."

http://www.naturalproductsinsider.com/blogs/insider-law/2015/09/fda-issues-warning-letters-on-powdered-caffeine.aspx

Daniel Fabricant, Ph.D., executive director and CEO of the Natural Products Association (NPA), said pure powdered caffeine is a legal dietary ingredient.

"I am unfamiliar with empirical evidence at FDA or elsewhere that would suggest that people would substitute directed conditions of use (i.e., greater than 1/16th of a teaspoon) due to measuring devices that weren't consistent with the labeling," Fabricant advised FDA officials Tuesday in an email. "Furthermore, the ability to weigh out 1/16th and 1/32nd of a teaspoon is commonplace in conventional culinary arts as explained by" online references that Fabricant provided the officials.

In a phone interview Tuesday, Fabricant expressed concerns that FDA's reasoning in the warning letters could have broader implications.

"They are saying people can't be trusted to measure things out" without the studies or data to support that idea, said Fabricant, who previously led FDA's Division of Dietary Supplement Programs. "If they can use that argument here, they can certainly use that on other products that contain caffeine and are used safely by millions of Americans every day."

If a person takes one-sixteenth of a teaspoon of powdered caffeine, the amount is "well under anything that any scientific body has said is harmful," Fabricant added.

Others in the industry—including the American Herbal Products Association (AHPA), Council for Responsible Nutrition (CRN) and United Natural Products Alliance (UNPA)—have adopted policies and guidelines that discouraged the sales of powdered caffeine to consumers by their members.

http://www.nutraingredients-usa.com/Regulation/NPA-s-Fabricant-on-caffeine-We-don-t-want-to-

get-into-a-position-where-Senators-are-using-a-court-of-public-opinion-to-regulate-the-industry
[NutraIngredients doesn't allow you to copy/paste directly from the article but the quote is more about the problem being people misusing the product.]

http://wshu.org/post/fda-calls-powdered-caffeine-unsafe

Dr. Daniel Fabricant, CEO of the Natural Products Association, said he doesn't agree with the FDAs claims against the powdered caffeine companies.

"We certainly respect the FDA's response and opinions and we understand the concerns surrounding pure powdered caffeine," Fabricant said. "I think the agency is missing its target claiming the product is dangerous because it can't be measured. They're not actually claiming the product is dangerous."

Fabricant said consumers shouldn't have a problem measuring out one-sixteenth of a teaspoon, regardless of how small it is. And the fact that two men overdosed isn't enough evidence that powdered caffeine is unsafe to use.

"It's a tragic reminder of an iron clad rule when it comes to these issues, which is to always read labels carefully on anything you put in your body and always consult a doctor or your health care provider when using any over-the-counter medicine or dietary supplement," he said.

From: Tave, Steven
Sent: Monday, November 07, 2016 4:10 PM
To: Welch, Cara
Subject: NPA and caffeine

Do you know if NPA has made any statements on the record about powdered caffeine as a dietary supplement?

Steven J. Tave
Acting Director
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
(301) 796-8608 (office)
(202) 631-1427 (blackberry)
steven.tave@fda.hhs.gov

From: Welch, Cara
To: Tave, Steven; Durkin, Robert (Robert.Durkin@fda.hhs.gov); Swift, Sibyl
Subject: RE: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source
Date: Thursday, January 12, 2017 12:03:00 PM

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http://www.ssciglobal.org/

Took me a while to figure out what SSCI actually is…I'm curious how it'll end up affecting the industry. Though to be clear, I'm not sure I see the direct link to safety.

From: Welch, Cara
Sent: Thursday, January 12, 2017 11:52 AM
To: Tave, Steven; Durkin, Robert (Robert.Durkin@fda.hhs.gov)
Subject: FW: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/NPA%20Letter%20to%20President-Elect%20Trump.pdf

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From: NutraIngredients-USA [mailto:newsletter@nutraingredients-usa.com]
Sent: Thursday, January 12, 2017 11:23 AM
To: Welch, Cara
Subject: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods onboard

The Natural Products Association has officially launched the Supplement Safety and Compliance Initiative (SSCI), with some of the largest retailers of natural products and supplements involved... Read

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NDIs, kratom, maternal and child nutrition, medical foods, health claims, and reducing the cost of healthcare are among the important issues affecting dietary supplements and the natural products industry in 2017, according to the Natural Products Association. .. Read

Sabinsa study supports DigeZyme's benefit in relieving post-exercise soreness

Sabinsa's researchers in Bangalore, India, found that the branded multi-enzyme complex ingredient DigeZyme improved the outcome measures related to delayed onset muscle soreness after exercise, compared to placebo... Read

Heard of the gut-brain axis? Meet the gut-skin axis...

Probiotic supplementation may improve adult acne appearance as researchers discuss the existence of a gut-skin axis in which the gastrointestinal area is targeted by bacterial strains to affect skin physiology... Read

Aquatic plant potential: Why duckweed could become a source of protein and omega-3 beyond South East Asia

Duckweed has long been consumed as an inexpensive protein and source of omega-3 in several South East Asia countries, but now researchers are questioning if it has the potential to be adopted by south Asian and even Western consumers too... Read

All News Headlines for: January December November

EDITOR'S CHOICE

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Quincy Bioscience, marketers of brain health product Prevagen, has been charged with making deceptive memory, cognitive improvement claims by the Federal Trade Commission and New York State Attorney General... Read

From: Welch, Cara
To: Tave, Steven; Durkin, Robert; Swift, Sibyl
Subject: RE: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source
Date: Thursday, January 12, 2017 12:16:00 PM

A few points from the letter.

- 2011 data from NBJ is old
- $1B on compliance when the industry makes $30B in sales doesn't seem that high...not sure how sales converts to revenue
- I appreciate he's promoting stronger enforcement and prosecution to the new administration
- And I appreciate the support re: kratom ☺

From: Tave, Steven
Sent: Thursday, January 12, 2017 12:13 PM
To: Welch, Cara; Durkin, Robert
Subject: RE: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

Here's really into the phrase "binding norm," isn't he?

From: Welch, Cara
Sent: Thursday, January 12, 2017 11:52 AM
To: Tave, Steven; Durkin, Robert
Subject: FW: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

http://www.npainfo.org/App_Themes/NPA/docs/press/Documents/NPA%20Letter%20to%20President-Elect%20Trump.pdf

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From: NutraIngredients-USA [mailto:newsletter@nutraingredients-usa.com]
Sent: Thursday, January 12, 2017 11:23 AM
To: Welch, Cara
Subject: NPA launches SSCI with GNC, Vitamin Shoppe, Walmart & Whole Foods / FTC outlines lessons for MLMs / Top supplement-related issues for PEOTUS Trump / DigeZyme may delay muscle soreness post-exercise / The gut-skin axis... / Duckweed as Omega-3 source

TODAY'S HEADLINES

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From: Welch, Cara
To: Tave, Steven
Subject: FW: Save the Date | Natural Products Association's The Big Natural
Date: Tuesday, November 28, 2017 12:34:00 PM

Better mark it on your calendar ☺

From: NPA's The Big Natural [mailto:info@momentumevents.com]
Sent: Tuesday, November 28, 2017 12:26 PM
To: Welch, Cara <Cara.Welch@fda.hhs.gov>
Subject: Save the Date | Natural Products Association's The Big Natural

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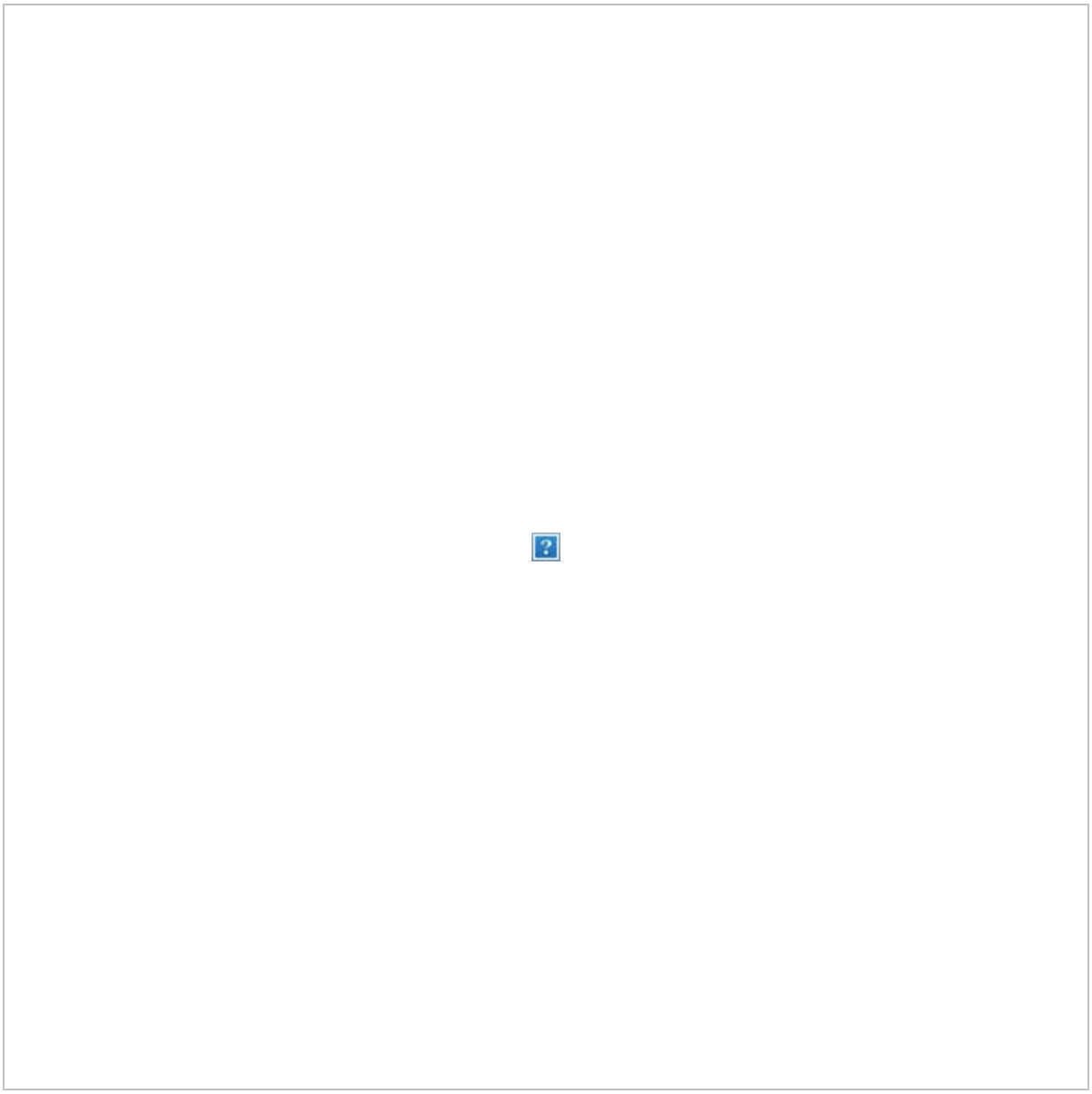

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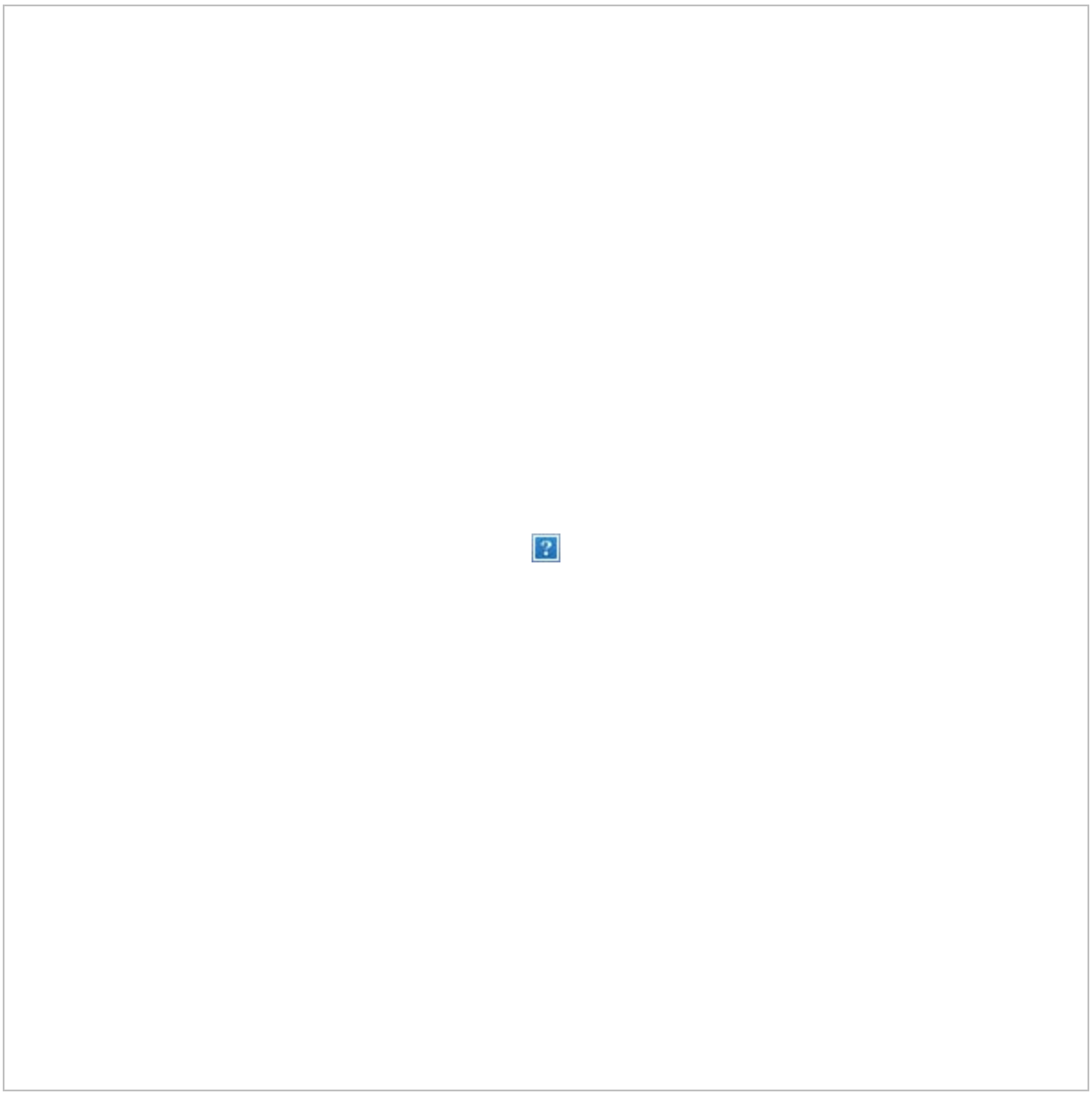

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From:	Welch, Cara
To:	Benjamin, Dianne; OC-OFVM-ExecSec
Cc:	Swift, Sibyl; Elkin, Ted
Subject:	RE: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Date:	Friday, February 06, 2015 12:32:00 PM
Attachments:	NPA Letter to Dr. Cara Welch.docx

The attachment states the same as the email but wanted to be sure it was shared as well
Cara

From: Benjamin, Dianne
Sent: Friday, February 06, 2015 12:31 PM
To: OC-OFVM-ExecSec; Welch, Cara
Cc: Swift, Sibyl; Elkin, Ted
Subject: FW: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction
Importance: High

All –

See the email trail. This correspondence should be logged into AIMS. Cara's draft must first be Center – cleared and we can discuss who should sign.

Looping in Ted.

Thank you –

Dianne

From: DeLancey, Siobhan
Sent: Friday, February 06, 2015 11:15 AM
To: Barrett, Kari; Benjamin, Dianne
Cc: Shapinsky, David
Subject: Letter from Natural products Association: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Hi Diane and Kari,

Cara Welch (acting director of the Division of Dietary Supplement Programs) just forwarded this letter she received from the Natural Products Association regarding the announcement Monday by the NY Attorney General's office regarding their testing of dietary supplement products for ingredient verification using DNA sequencing technology.

I wasn't sure who to send this to for tracking and coordination of a response, so am including both of you here.

From: Welch, Cara
Sent: Friday, February 06, 2015 10:43 AM
To: DeLancey, Siobhan
Cc: Harper, Kristina; Elkin, Ted
Subject: FW: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Siobhan, this is the letter I rec'd from NPA re: the NY AG topic. I realize this isn't as timely as the press inquiries with 2 hour deadlines but eventually we'll have to respond.

Tina, just wanted to keep you in the loop as well. Let me know if you want to discuss this.

Cara

Cara Welch, Ph.D.
Acting Director
Division of Dietary Supplement Programs
CFSAN/FDA
Direct: 240-402-2333
Mobile: 240-762-8634
cara.welch@fda.hhs.gov

From: Lauren Cohen [mailto:lcohen@npainfo.org]
Sent: Thursday, February 05, 2015 5:53 PM
To: Welch, Cara
Cc: Harper, Kristina
Subject: Regarding scientific validity of DNA methods for botanical ingredients after extraction

Lauren Cohen
Vice President, Public Relations & Communications
Natural Products Association
Washington, DC

February 5, 2015

Cara Welch
Acting Director
Division of Dietary Supplement Programs
Food and Drug Administration
College Park, MD

Dear Dr. Welch,

On Tuesday, February 3, New York State Attorney General Eric Schneiderman ordered four major

retailers to stop selling store-brand herbal supplements. All four retailers have received cease-and-desist letters demanding that they halt the sales of these supplements because a third-party testing lab used DNA barcoding to identify botanical ingredients, listed on the label, through a type of "genetic fingerprinting", and discovered evidence to the contrary. A total of 19 out of the 24 products tested supposedly contained DNA that was either unrecognizable or from a plant other than what was claimed on the label.

The Natural Products Association and the dietary supplement industry as a whole are concerned about this issue on several levels. There is no question that DNA finger printing is a powerful tool for natural product authentication, including raw materials before extraction. The information provided by the New York Attorney General fails to mention the listing of botanical extracts as dietary ingredients in these herbal supplement products. Botanical extracts involve the use of alcohol or other solvent to extract the final dietary ingredient from the source botanical. The use of DNA barcoding methodology on extracts of raw ingredients is neither a good, better, or best standard of practice in the dietary supplement industry.

We ask the Food and Drug Administration to opine on whether this DNA barcoding technology is appropriate, sensitive, specific and scientifically valid for routine use by the dietary supplement industry to definitely identify botanicals used as the starting source material to create botanical extracts. If it is not commonly used for extracts of raw botanicals in finished products to identify botanical sources, why is this methodology being given credibility at this time. The concern is that DNA will be sufficiently degraded during the extraction and manufacturing process that intact DNA markers specific to a particular botanical will not be detected. Therefore, is the technology fit for purpose in botanical identity with regard to routine use in dietary supplements containing botanical extracts?

Thank you for your attention to this important matter, and we hope the FDA can shed light on the scientific validity of this study.

Sincerely,

Lauren Cohen
VP, Public Relations & Communications
Natural Products Association
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Washington, DC 20009
Phone (202) 204-4722
Fax (202) 223-0250
lcohen@NPAinfo.org
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